Naval Submarine Medical Research Laboratory

NSMRL Report 1214 25 JULY 2000

NOISE REDUCTION STETHOSCOPE FOR UNITED STATES NAVY APPLICATION

by

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Released by
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Acknowledgment and Disclaimer
This project was conducted under Naval Medical Research Development Command Research Work Unit 64771N-M00933.002-5624. The opinions and assertions expressed in this report are those of the authors and are not to be construed as official or reflecting the views of the Department of the Navy, the Uniformed Services University of the Health Sciences, the Department of Defense, or the US Government. This research has been conducted in compliance with all applicable federal regulations governing the protection of human subjects in research.

The authors wish to acknowledge Derek Schwaller, our biomedical engineer, for his tireless, conscientious achievements in instrumentation, data gathering, digital editing and signal analysis. Special acknowledgment is due to Surgeon Commander Steven Ryder, Royal Navy for invaluable guidance during the design of this research and clinical evaluation of our selected "patients". We greatly appreciate the voluntary efforts of LT Michael Waltz, MC, who took over as medical monitor for LT Jackman MC, and who, was not only able to enlist our highly trained medical listeners on short notice, but also endured at least five hours as a subject himself. We appreciate the efforts of all our participants for their conscientious performance, patience and endurance in such a demanding task. We are intensely grateful to Lynne Marshall for her extensive editorial efforts as a reviewer to help make this report more clearly convey our findings.

This research is dedicated to Thomas E. Hanna, a *Braveheart* who led by example. Thanks for your confidence and support from the onset.

Joseph S Russotti, is Principal Investigator, and Thomas P. Santoro, LT Robert Jackman, MC, LT Deborah White, MSC, are all Associate Investigators on this project at the Naval Submarine Medical Research Laboratory. The co-authors are listed in alphabetical order since each contributed equally to this research project.

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SUMMARY PAGE

The Problem: Conventional stethoscopes cannot function effectively unless ambient noise is maintained at approximate examination-room levels. This serious limitation inhibits diagnosis and monitoring of patients in a variety of common military medical situations: in field hospitals, in high ambient noise environments such as engine rooms, in vehicles such as ambulances, fixed and rotary wing aircraft, or in hyperbaric chamber treatment facilities. Trying to measure blood pressure, determining if a faint heart-beat is present in a casualty, or listening to respiratory events can be nearly impossible under field conditions.

The Approach: The objective of this project was to evaluate commercial off-the-shelf (COTS) products and recommend one or several compact noise-reducing/canceling stethoscopes for field, medical-transport, and shipboard use, in *moderately* noisy environments (up to 90 dB SPL). At the onset of this project a working group was convened to assess Navy need and requirements for a noise-reducing stethoscope for casualty care and general medical use. In general terms, given present and projected COTS state-of-the-art technology, a *modular* approach using a simpler device tailored to the application, will be more cost-effective, for general-issue, than a single device. We selected three such simpler devices for laboratory testing using both the listening-headsets provided, and a highly accurate active noise cancellation (ANC) headset.

The Findings: Laboratory data show exceptional performance of noise reduction stethoscopes in detection of heart/lung sounds, especially in noisy environments up to around 95 dB SPL. Of greater relevance, a conventional device is unable to detect *abnormal* breath sounds when the noise field exceeds about 76 dB SPL; *abnormal* heart sounds can only be detected at levels below 81 dB SPL. For one of the two best COTS devices, the detection advantage over a conventional stethoscope for these *abnormal* sounds is 17 dB for breath and 12 dB for heart. Evaluation of the results from field data on *normal* heart/breath sounds confirmed their utility and provided user-suggestions on possible improvements in design. Contracted pre-production prototypes address several field-test recommendations.

The Application: Based upon the results of this laboratory study and field analyses, we recommend two COTS devices for immediate military field use in environments below 95 dB SPL, and suggest a prototypic device as a candidate for Small Business Research Initiative (SBIR). We also recommend that these devices be used for their ability to provide the best possible electrical signal for telemetry and also as a signal source for COTS software programs that allow acoustic records of patient pathology. Recommended models are the SmartMed™ Stethoscope by C.F. Electronics and Sonar Sound ™ model 160 by Flow Scan.

ADMINISTRATIVE INFORMATION

This report was conducted under Naval Medical Research and Development Command Research Work Unit 64771N M00933.002-5624. The views expressed in this report are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. government. This report was approved for publication on 25 July 00 and designated Naval Submarine Medical Research Laboratory Report 1214.

ABSTRACT

Conventional stethoscopes cannot function effectively unless ambient noise is maintained at approximate clinical levels (approximately 70 dB SPL). This serious limitation inhibits diagnosis and monitoring of patients in a variety of common military medical situations: in field hospitals, in high ambient noise environments such as engine rooms, in vehicles such as ambulances, fixed and rotary wing aircraft, or in hyperbaric chamber treatment facilities. Trying to measure blood pressure, determining if a faint heartbeat is present in a casualty, or listening to respiratory events can be nearly impossible under field conditions. Technology is immediately available to dramatically reduce this shortfall. The objective of this research was to evaluate several compact noise-reducing/canceling stethoscopes for field, moderately-loud medical-transport, and shipboard use in noisy environments. Three commercial off the shelf (COTS) noise reducing stethoscopes, having electronic outputs, were evaluated quantitatively in a controlled laboratory study. Laboratory data on detection of vital sounds in operationally-relevant sound-fields showed the devices' ability to adequately present *abnormal* heart and breath sounds in 90 to 95 dB SPL. By their design these devices could tolerate higher levels of environmental noise that normally would interfere with such detection. This is a significant improvement in the tolerable ambient sound-field over an average 76 dB SPL upper limit for detecting *abnormal* breath sounds, and an average 81 dB SPL upper limit for detecting *abnormal* heart sounds, when using a conventional device. After laboratory and operational evaluation, we are able to recommend two available COTS devices for military use, and to suggest a prototypic device, (a vastly miniaturized version of one of the two devices we recommend) as a candidate for Small Business Research Initiative (SBIR). It is also our recommendation that these devices be used for their ability to provide the best possible electrical signal for telemetry and also to any of the various software programs that allow acoustic records of patient pathology.

KEY WORDS

Stethoscope, Noise Reduction, Noise Reducing Stethoscope

NOISE REDUCTION STETHOSCOPE
FOR UNITED STATES NAVY APPLICATION

INTRODUCTION

Since its initial development by Laennec in 1819 (1), the stethoscope has provided physicians with an invaluable diagnostic tool. This simple sound-powered device acoustically couples the small movements collected over a large area into relatively larger movements on the surface of the eardrum. By virtue of the differences in surface area between eardrum (55-90 mm^2) (2) and the pickup, (1300 mm^2) an acoustic gain is achieved. This elegant device continues to be a mainstay diagnostic tool to the present day and is a readily recognizable icon of the medical profession. It was originally designed for listening to sounds in the chest, heart and abdomen but other uses have been developed since its invention. In 1905 Korotkoff (3) published a report on a procedure that used the stethoscope to provide a measurement of blood pressure, both systolic and diastolic. Sekhar and Wasserman (4) developed a novel stethoscope that couples to the human eyeball to detect intracranial vascular lesions. More recently, Gallo *et al*. (5) used the stethoscope in reverse to measure sounds in the ear canal to detect tempero-mandibular joint abnormalities.

The original stethoscope developed by Rene Laennec, approximately 180 years ago, was a monaural (one ear) mechanical instrument. Demonstrating the elegance of the original concept, only minor design changes have been subsequently incorporated. George Camman developed the binaural stethoscope approximately 30 years later, which increased the audibility of body sounds by feeding the signal to both ears. Blocking the ambient airborne sound to the occluded ear canals effectively decreased interfering *external* noise. The U.S. Air Force introduced the analog electronic amplifier stethoscope in 1955 to improve auscultation by the amplification of low-level body sounds. Unfortunately, this model also amplified surrounding noise as well as body sounds. In 1991, Ljungvall and Thulin (6) reported on their work to modify the stethoscope head into a smooth surfaced thin wedge shape for "hands-free" operation under the edge of a blood-pressure cuff. This research identified a major weakness in the conventional stethoscope: its sensitivity to the movements of the patient, hand tremor of the examiner, finger and nail movements, and self noise of the stethoscope's pickup-head moving against skin and against the pressure cuff during blood pressure measurement. Other limitations include the severe attenuation of sound transmission as a function of frequency, and the maxima and minima at very specific frequencies due to tubular resonance effects and differences in transmission properties observed between different stethoscopes (7).

Interfering noise

Emergency medical situations often occur in noise environments that preclude the use of the conventional stethoscope. Brogan *et al*. (8) reported that The Military Aircraft Command in 1966 recommended that an electronic stethoscope be developed for use "...aboard aero-medical evacuation aircraft, since listening procedures were extremely difficult, if not impossible with regular stethoscopes." They reported their efforts to improve the signal-to-noise ratio by devising both an acoustically shielded pickup transducer and headphones, and by band-limiting the amplified signal. The belt mounted electronics package was quite large and clumsy at 6.75" x 6" and approximately 2" thick. While they reported improved performance, no mention is made of actual noise attenuation characteristics in their report. In 1969 Allred *et al.* (9) reported development and evaluation of two electronic stethoscopes of novel design which they later incorporated into a single device of conventional size and shape. The first design shifted the frequency of Korotkoff sounds and eliminated acoustic coupling between pickup and earpieces. The second stethoscope eliminated all acoustic coupling but avoided frequency shifting.

Pasic and Poulton (10) reported on the increasing use of aero-medical transportation and concomitant increased intense noise exposure of helicopter pilots, aircrew and transported patients. They warn, "Noise makes impossible the use of the standard stethoscope to auscultate breath sounds, heart sounds or Korotkoff's sounds." In 1990 Bishop (11) reported on the inability to detect arterial sounds using a conventional stethoscope during a domestic commercial flight. This was confirmed by Cottrell and Kohn (12), who reported similar findings derived from their earlier 1989 published study of emergency treatments during commercial flight. A study by Hunt *et al.* (13) attempted to assess the capabilities of a traditional and an amplified stethoscope during air medical transport. They concluded "...flight nurses using a traditional or amplified stethoscope are unable to hear normal breath sounds during flight in an MBB BO-105 helicopter".

Conventional stethoscopes (mechanical or electronic) cannot function effectively unless ambient noise is maintained at normally encountered clinical levels (which are approximately 70 dB SPL[1]). This serious limitation inhibits diagnosis and monitoring of patients in a variety of common medical situations: in hospital emergency rooms and trauma facilities (65 dB SPL to 80 dB SPL); in emergency service vehicles such as ambulances, fixed and rotary wing aircraft (85 to 140 dB SPL); or in areas where patients are attached to pulmonary ventilators, in neonatal incubators, or in hyperbaric chamber treatment facilities (75 to 95 dB SPL) (9, 10, 12, 14, 18).

As a result of these reports and technological advances in modern computer and digital technology, electronic stethoscopes of varied types and capabilities are currently at various stages of development. The digital electronic stethoscope was introduced about 6 years ago. It is a microphone-transducer-amplifier concept with a digital signal processing capability built into the system. Unfortunately, it too has the same inability to function in noisy environments as the analog stethoscope. The search for a more effective stethoscope for use in high noise conditions persists (13).

Currently available technology

Currently, cumbersome prototype electronic devices exist for ascultation in noisy environments. Depending on how they reduce the noise, the devices are commonly referred to as: active noise cancellation (ANC), active noise reduction (ANR), and noise reduction (NR) stethoscopes. Within the group of acoustic devices that reduce noise using active means (electronic signal modification), ANC devices use an *inverted* real-time analog signal from another microphone directly to remove noise by cancellation (15). In ANR devices a transfer function is digitally applied to the real-time sensor microphone to mimic the response characteristics (bandwidth and spectral shape) of a conventional stethoscope-head to actively reduce noise. The transfer function may be a fixed equation or it can be derived from a control microphone that monitors signal and noise in real time. More elaborate procedures such as those reported by Zacharias *et al.* (16), Suzuki *et al.* (17), and most recently by Patel *et al.* (18), use adaptive filter techniques to modify the transfer function to compensate for differences in the noise transmission path through different points on the body. Other simpler NR electronic devices utilize pickup transducers immune to airborne noise for example, by translation of skin torsional forces (via a piezoelectric *thin-film* sensor) to an acoustic signal, or utilize noise attenuating materials around the sensor to reduce the interfering airborne sound on the sensor. Applying acoustic signals generated outside the range of human hearing, Kopczynski *et al.* (19) reported on an ultrasonic blood pressure monitoring device developed by USAF School of Aerospace Medicine that employs the "Doppler shift principle to detect blood flow and arterial

[1] Decibels in Sound Pressure Level where 0 dB SPL is relative to 20 micro (μ) Pascal. This SPL reference will be used throughout the report.

wall motion... rather than detecting Korotkoff sounds." The device detects the Doppler shift in the *ultra*-sonic signal and converts it into an audible sound indicating arterial wall motion. The audible signals appear and disappear in equivalent manner to Korotkoff cues. They concluded the device proved to be effective in eliminating the effects of in-flight noise and vibration on blood pressure measurements.

As one might expect, the most sophisticated devices are costly and, by incorporating additional processing hardware, are usually physically larger (far too large for field-pack applications). The assessed devices all have specific advantages and drawbacks related to cost, size, and complexity of transducer placement. Presently, no one device is ideal for universal use. The majority of devices are either proof-of-concept prototypes using rack mount hardware, or in Phase II (initial hardware development). They are not at a production stage. It should be noted that all of the developers of the most elaborate multiple-sensor stethoscope devices have abandoned their efforts at further development while the simpler devices have evolved into marketed products.

OBJECTIVE

In an effort to address Navy medical needs**,** Naval Submarine Medical Research Laboratory (NSMRL) has undertaken the identification of ascultation requirements identified by the operating forces and an assessment of currently available commercial off the shelf (COTS) devices to best meet those requirements.

Along with the objective of providing the best commercially available technology, was the crucial need to understand and define exactly the present and future needs of our end-users. To achieve that end, a Noise Reducing Stethoscope Working Group Meeting was convened in Washington, D.C. in September of 1996. Participants were a mix of personnel from operational theaters as well as operating forces and manufacturers. The plan involved identifying our customers, and having them identify their needs, but with knowledge of what was commercially available and what was potentially feasible. Representatives came from the Naval Surface Force U.S. Pacific Fleet, Naval Special Warfare Command (NAVSPECWARCOM), United States Uniformed Health Services (USUHS), Joint Medical Readiness Training Command (JMRTC), U.S. Special Operations Command (USSOCOM), Naval Aerospace Medical Institute (NAMI), Bureau of Medicine and Surgery (BUMED) Codes 21, 22, and 23**.** Additional members were acoustic, operational-medicine and auditory researchers from Penn State Applied Research Laboratory and from NSMRL. Based upon the presentations, a consensus of operational needs and requirements evolved. A synopsis of that information is described in ***Appendix A***.

RESEARCH PLAN

Given the opportunity at the Noise Reducing Stethoscope Working Group, the operating forces identified their *needs* for a device *far* beyond what was commercially *feasible* within the time-frame of this project. After attending manufacturers demonstrated their existing technology, it was clear that no current or immediately imminent device would fill all the *anticipated* needs of operational medicine. However, the device specifications, which were circulated back to the manufacturers, were of value in identifying the direction toward which manufacturers needed to advance. ***Appendix B*** details the physical and other specifications that the *ideal* instrument of the *future* will have to meet.

Clearly, the *primary* **(**and most restrictive**)** criterion was that the device not be much larger than a conventional stethoscope. The operating forces made clear that they were willing to

sacrifice universality of application (i.e., to encompass intense airborne and structurally transmitted interference as encountered in helicopters) for a smaller far less expensive device that would have a far greater chance of being issued to all medical personnel. Situations of intense noise were far less prevalent than moderate noise, and in many intense noise situations (e.g. rotary-wing aircraft) the requirement for a tiny portable field device was less critical. Other methods (larger, specialized, more costly, non-acoustic etc.) could be used to monitor vital-signs in these environments. The group unanimously agreed that a less, not more, complex device was desirable for general issue. It was decided that this general-issue device should function well in environments up to 90 dB SPL.

So, given that the Working Group's *ideal* stethoscope was a highly sophisticated data-processing device that was technologically possible but, because of size constraints, far into the *future*, what could be provided in the interim?

The modular approach

The *near term* COTS noise-reducing electronic stethoscope must have the advantages of the acoustic stethoscopes, without the limitations. Of *primary* importance, it must be small, dependable, and simple to operate. There should be accurate and adjustable amplification, little ambient artifact noise, and minimal instrument manipulation artifact noise. The earpieces or sound transducers should be comfortable, adjustable, and provide excellent acoustic isolation from ambient sounds. There could be a bell and a diaphragm-filtering mode or some equivalent. It must also have an ergonomic design and, most important, it must be operationally acceptable. Near-equally important, it must also be inexpensive enough for general-issue. More to the point, it must be a compromise of general utility and dependability over high technology. One of the best ways to that goal is a *modular* approach. We need a small dependable device that wastes none of its power consumption or valuable component *volume* or *cost* on unnecessary processing. For modular application, it *must* have an electrical signal output, but given modern analog to digital processing, a clean analog output is all that is needed. Additional processing can be done outboard to conserve battery power in our primary device. We need a primary device that everyone can be issued and can not only operate more effectively with, but one that serves as the noise-immune front-end for the rapidly evolving world of miniaturized signal-processing hardware. As a *modular* interfaced component, miniature hand-held CPU devices and software can instantly upgrade without obsolescence. If a manufacturer can optimize such a sensor device, and price it competitively it can become general-issue. Clearly it cannot work miracles. It sacrifices intense noise situations and the ability to cancel structurally transmitted internal- body noise for size, general-issue and dependability.

The decision herein to seek a less complex device to be applied in a *modular-configuration* is predicated on the fact that *much* of the noise that interferes with ascultation enters into the process at the sensor-head and also at the coupling to the ear. In 1993 Zacharias *et al*. (16) described a model for the noises "impinging on the medic/stethoscope/patient" at three separate points. Noise N_1 acts on the medics auditory system bypassing the stethoscope. Noise N^s_2 acts on the stethoscope itself, from the contact point with the patient, to the medic's earpieces. This noise spectrum is modified by the transfer-function of the stethoscope. Finally, noise N^p_2 is the noise that has entered into the patient's body and is modified by the acoustic transfer characteristics of the trunk or torso. Given this background, with a modular approach the operator could tailor the noise-reduction potential (and cost) of the product to the application. In fact for moderate levels, noise-reduction solely at the pick-up sensor might suffice. The manufacturer's inclusion of an ANC headset in the original COTS would likely have resulted in added noise-reduction benefits essential for some users, but would require an additional cost. Inclusion of state of the art (SOTA) ANC headsets could price the product well out of the commercial stethoscope market. Similarly, there is not a major commercial market for a specialized stethoscope with an insert-

earphone (earpiece) that can function under a chemical warfare body suit. With a modular approach, specific military needs can be addressed.

Within our solution was the requirement to tailor the COTS device to the application. We evaluated the device's intrinsic ability to extract information in operationally relevant situations. We parsed out *pick-up and signal extracting* capability from both headset or earpiece *fidelity* and headset or earpiece *noise reduction* capability. To accomplish this, we tested the product as supplied, and also with other noise-attenuating headphone combinations that would adapt the device to a broader operational use. COTS products were modified by changing their signal output characteristics in ways that would most likely significantly enhance their ability to function in noise. There were no modifications to their electrical output, only the fidelity and/or noise-reduction capability of the listening headphone. It must be noted that any noise-reduction achieved by the device is done before the signal is fed to the earpiece. To maintain that noise reduction, the appropriate transmission to the ear is also critical but independent of the methods used to reduce noise at the pick-up. Most important, we already knew that ANC headsets were an optimal method of reducing noise when we present an acoustic signal to the ear.

In terms of optimal bandwidth[2] of acoustic stethoscopes, perhaps the most extensive evaluation of their transmission characteristics was conducted by Ertel *et al.* (20), using a Zwislocki ear simulator to match the acoustic impedance of the ear. Twenty-eight unaltered commercial stethoscopes were tested and showed a 20 Hz to 3 kHz bandwidth was achievable (21). Ertel *et al.* concludes, that "…it is yet to be proven that there are significant cardiovascular sound components above 3 kHz" but strongly recommends that devices with better high frequency response be selected.

Product evaluation requirements

With the objective of ranking and rating different products for their ability to extract vital sounds with immunity from airborne environmental noise, we need to meet several criteria:

1) *Ability to accurately re-create airborne sound*
The ability to spectrally re-create several operationally representative noise sources in the laboratory over a range of discrete *steps in level* provides a metric for comparative product performance. We can step the level of the environmental-noise signal from below, to well above, the *true* environmental-level to determine detection threshold of various visceral sounds for medically trained listeners using a specific device. This provides a relative measure of intrinsic product effectiveness in reducing interfering airborne noise in a generic operational environment.

2) *Ability to measure detection of the relevant sound*
By using *adaptive tracking* tasks to determine the maximum airborne sound-level at which the sound of interest is detectable, we have a metric that is extremely sensitive and highly reliable (22). The task uses a time-window to validate subject responses. The adaptive aspect forces the subject response to a specific level of performance accuracy (23).

3) *Ability to present the same body sound to each listener*
Perceptual research of this nature requires that each listener be presented with *exactly* the same stimuli. In this case, device placement is also a critical parameter that can vary. As a result, all listeners need to hear the same placement on the same subject located exactly in the same sound -field environment.

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[2] The difference between the upper and lower cutoff frequencies. The range of frequencies that can contain or describe the signal.

Using digital storage devices, recursive recording provides a methodology to faithfully recreate the stimulus (in this case, the vital-sign embedded in interfering environmental noise). In this application, we stored the electrical output of *each* device under each condition: visceral-sound type **x** device **x** environmental-noise type **x** level of noise. This allowed replay of the signal over the manufacturer's supplied earpiece with no change imparted to the intended signal. This significantly maintained low variability across listening conditions.

These laboratory procedures gave us a reliable quantitative method of ranking device performance based on detection of sounds. Field use provided insight on how well the COTS device functions in a field environment with noise.

Human subjects were used as vital-sounds sources because of the novel nature of the pick-up sensors. Vital-signs training-devices are available that generate both normal and abnormal visceral sounds. However, such devices use artificial skin with a loudspeaker beneath, which could likely confound the performance of a manufacturer's noise-immune non-acoustic pick-up.

Product selection

Finally, after identifying available COTS items, we selected three devices. The three COTS devices can be seen in ***Appendix E***. Each device met our requirements of being small enough to be carried on the body, with a pickup head not much larger than a conventional stethoscope. Of utmost importance, each device had an electronic output separate from its own headset output. In our preliminary listening tests, each device seemed to perform better than a conventional stethoscope in reducing moderately-loud levels of outside noise. As we gathered our environmental recordings, several of the devices tested were still under development. We were fortunate to incorporate the final improved models into our vital-signs data gathering tests. The devices chosen were: the SmartMed™ Stethoscope by C.F. Electronics (Device 1), the Sonar Sound ™ model 160 by Flow Scan (Device 2), and the E-Scope™ Electronic Stethoscope by Cardionics (Device 3).

The SmartMed uses a special sound-dampened acoustic transducer connected to a 3.75 x 1.75 x 6.75 inch case which has a .25 inch stereo phone jack into which a Sony closed-circumaural (around the ear) headset is connected. The Sonar Sound uses a unique polyvinyl sheet-material, which generates an electrical signal when torsionally flexed, as the sensor. A 1.5 square-inch pad of this material is housed beneath a sensor-head, designed to be clasped between two extended fingers. A short cable connects the head to a 2.5 x 0.93x 4.38 inch case, which controls the signal cabled to a headset with stethoscope-like earpieces. The E-Scope uses a conventional looking diaphragm coupled to an attached microphone-element which is cabled to a 1.0 x 2.38 x 3.75 control box. Conventional stethoscope earpieces are acoustically connected to a transducer within the box.

These devices were evaluated in the laboratory as manufactured, and also with the device output properly interfaced to a Bose Aviation Series I Commercial ANC headset. In that configuration the letter A was appended to the device number. Given the three devices as manufactured and paired with the ANC headset, the seven test device designations were 1/1A (SmartMed™ Stethoscope), 2/2A (Sonar Sound™ Stethoscope), 3/3A (E-Scope™ Stethoscope), and standard (Littman™ *Classic II* stethoscope).

PHASE 1: LABORATORY EVALUATION

METHOD

Subjects

Fourteen highly experienced medical personnel were used as listeners. The sample population consisted of two medical doctors (U. S. Navy, and Royal Navy), with the remaining twelve U. S. Navy Hospital Corpsmen with hospital-ward experience using stethoscopes. Two were emergency medical technicians (EMTs) during their off-duty. Several were Independent Duty Corpsmen (IDCs). All had normal hearing in at least one ear as measured by routine audiometry. Normal limits were defined as having no losses greater than 25 dB HL over the range of audiometric test frequencies: 125, 250, 500, 750, 1k, 1.5k, 2k, 3k, 4k, and 6k Hz

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Experimental Design

Auditory detection of normal and *abnormal* heart and breath sounds were compared under three operationally-relevant intense-noise conditions using one standard, and six experimental, stethoscope-listening conditions. The three relevant environmental airborne-noise conditions recreated were: **A**) a field-hospital 100 kilowatt generator (KWG); **B**) the patient area inside a moving HumVee soft-top field-ambulance (HUV); and **C**) the interior of an airborne C-130 Transport (C130). During each of four randomly-assigned listening sessions, one session per day, subjects heard a different vital-sound (normal or abnormal heart, or normal or abnormal breath) presented within a random serial order of the three noise environments. Each daily listening session used a random order of seven stethoscope conditions repeated across the three environmental conditions. These stethoscope conditions consisted of a standard stethoscope and three COTS stethoscopes tested as supplied, and also tested with a COTS active noise cancellation (ANC) headset substituted for the supplied listening earpiece (headset). What was measured was the maximum level of airborne noise at which each device could enable detection of the four visceral sounds. All subjects heard *all* conditions. The repeated-measures design ensured that each medically-trained listener served as his/her own control across the various test-listening conditions.

Environmental Simulation

A high-intensity sound system was instrumented to operate within a 30 x 16.5 x 11 foot high cement-block-walled reverberant room. The system consisted of four speaker arrays, each containing two 18 inch drivers, a 15 inch driver, and one 4 inch diameter titanium horn-driver. Each transducer was independently powered, by a configuration of Crown amplifiers capable of producing 1,310 watts RMS in each of 4 channels with THD at less than .02% at rated power. Each channel of the system was fed by a separate channel of a Digidesign Pro Tools III digital hard disk recorder/editor. Four analog output channels of a Digidesign 888 interface were distributed to the amplifiers of each array through a pair of Rane AC-23 active crossovers. Just ahead of the AC-23 inputs, each of the channels was digitally controlled by a separate Wilsonics model PATT attenuator.

Environmental Sounds:

Field recordings were made at various operationally relevant sites using precision recording equipment. Airborne-noise, received by a Bruel and Kjaer (B&K) type 4191 *free-field* ½ inch diameter condenser microphone with type 2619 preamplifier and 227 battery-power supply, was recorded on either a Tascam DA-P1 or a Panasonic SV-250 portable DAT recorder for post-analysis. The microphone-preamplifier assembly was attached to a vibration-isolated extension handle to remove and decouple the data-gatherer from the measured sound-field. Microphone placement was at a region representative of the position of a listener's head.

At the start of each recording, a B&K sound level calibrator type 4230 was coupled to the microphone to produce a 1 kHz tone at 93.8 dB SPL re 20 micro (μ) Pascal. By setting the DAT recorder input-level once for the calibration tone, all subsequent recordings can be referenced to that sound pressure level.

DAT recordings were spectrally analyzed using either a Data Physics ACE or DP-430 FFT signal analyzer. Root mean square (RMS) averages of the energy measured in 1/3-octave bands were calculated. The resultant overall RMS, A-weighted, and 1/3-octave band data were used to recreate these recorded signals at operationally relevant levels in the reverberant field test facility. Relevant environmental signals were transferred to the Digidesign system and edited to form a continuous loop. Once a seamless edit was achieved, three additional copies were generated, each randomly shifted in time from the original. These four sound files were separately and simultaneously fed to the speaker arrays to create a homogeneous non-directional (diffuse) sound field.

Vital-Sounds Signals

In this first phase, "patients" were used solely as a source of normal and *abnormal* body sounds. Volunteer "patients" were placed in the specially designed sound room, which reproduces operationally relevant noise environments, while visceral sounds were recorded using each stethoscope as the sensor. Normal heart and breath sounds were both taken from the same healthy male. Abnormal heart sounds were recorded from a male diagnosed as having aortic stenosis secondary to rheumatic fever as a child. Abnormal breath sounds were gathered from a female exhibiting acute asthma recorded just prior to medication. The visceral-sounds were chosen by two medical doctors to be representative of vital sounds important for ascultation. Both *abnormal* sounds were chosen for their relevance and difficulty.

Recording of Vital-Sounds Stimuli

Prior to data collection, "patients" wearing appropriate hearing protection were placed on a stretcher in the diffuse-field test chamber and the pick-up sensor of the stethoscope device to be tested was carefully moved in location on their body until maximum signal levels of internal body sounds were obtained. The calibrated sound field in the room was *on* at some predetermined low starting level. A medical doctor or independent duty corpsman (IDC) adjusted the pick-up-head position as they listened to the output of the device over ANC headphones. Once adjusted, the "patient" was signaled and the sound field was raised in 2 dB steps, starting at 66 dBA[3] every 10 seconds to maximum level, while device electronic output was digitally recorded. The electronic output recorded was the same signal that was fed to the headphone. Ambient sound in the room was raised to no more than 94 dBA. Total data collection time for one sound-field was less than 3 minutes (15, 2dB steps X 10 seconds per step = 150 seconds). Data collection was resumed using another sound-field following this same procedure until vital-signs recordings for all three environmental sources were recorded using that same stethoscope device.

Since the environmental-sounds generated in the test chamber were recordings, no unexpected sounds or intensities could occur. All signals were accurately monitored during data collection. Because of the brief duration and hearing protection, noise exposure was well within the Hearing Conservation Guidelines put forth in DOD instruction 6055.12 (24)

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[3] During all noise exposure conditions, sound levels were monitored in dBA, where the A-weighting scale is applied to better assess the effect of the airborne sound on the human listener's hearing. However, for assessing the actual levels of the environmental sounds, we were interested in the unweighted dB SPL values since this better described the energy in which the sensors were required to extract the signal.

The electronic outputs of three COTS stethoscopes were used in data collection. In addition, as a comparison, the acoustic output of a Littmann Classic II Stethoscope with soft-sealing eartips was recorded through ears of a specially treated acoustic test manikin. The earpieces of the Littmann were carefully fitted into the ear canals of a Kemar® manikin. This device, equipped with Zwislocki ear simulators that model the acoustic impedance of the ear, has been used extensively in our headphone research (25, 26). Pliant bags of lead shot placed within the manikin were used to block sound transmission to the calibrated microphone "eardrum" from pathways other than the ear canals. Electroacoustic test results confirmed our ability to attenuate such transmission at 40 dB or greater from 160 Hz to 500 Hz, 50 dB or better from 500 Hz to 2 kHz, and 60 dB or more from 2 to 15 kHz. A specially designed bridged-T filter, proposed by Killion (27), was employed to properly remove the filtering effects of the ear-simulators for accurate reproduction at the listeners ear. Levels presented at the eardrum were identical to those normally available using the stethoscope. Recordings from the three experimental devices and those recorded from the Littman stethoscope were all made using live patients as our source of visceral sound.

Source Stimuli

To recap, stimuli were digital sound files of vital-signs signals collected on human patients in three operationally relevant noise-fields (at 15 different levels of the environmental noise-field) using a standard stethoscope and three experimental models. A 3x15matrix of sound files for each vital-sign signal was stored on hard disk for rapid access. The vital-sign signals were normal breath and heart sounds and *abnormal* breath and heart sounds. The normal sounds were taken during different sessions from the same patient. The two *abnormal* sounds were gathered from two different patients.

Stimulus Generation

A 16 bit digital-to-analog converter (DAC) with a 48-kHz sample-rate was used to generate a repetition of the previously digitized stethoscope sound sample (sound file) from the matrix. These parameters meet or exceed those recommended for professional audio applications (28). Analog to digital (AD) and digital to analog (DA) processes were implemented using a Data Translation DT2823 digital converter board resident in a PC. During both digitization and playback, a Rockland model 2783 140 dB/octave low-pass filter, with cut-off at 22 kHz, was used as an anti-aliasing device.

Stimulus Presentation

As described above stimulus generation was accomplished using a PC based DAC. For automated testing and data collection, a second PC was used to control the presentation of those signals and also control the level of environmental sound generated in the room. Algorithms to implement the test procedure and control stimulus selection and level, target[4] onset and duration and assess listener response were executed to implement the test procedure described below.

Adjustment of the environmental sound-field in 2 dB steps was digitally controlled through the four Wilsonics model PATT programmable attenuators to reproduce the appropriate room intensities prior to and during each stethoscope listening trial. Simultaneously, a TDT electronic switch, under PC control, gated the appropriate level vital-sounds signal, accessed from the stored matrix, for the stethoscope being tested.

Test Procedure

Subjects listened to visceral sounds recorded through the stethoscope devices in the various

[4] The embedded signal to be detected. In this case visceral sounds embedded in *environmental* and *internal* body-noise.

noise environments using the headset provided by the manufacturer as well as an ANC headset. Target detection threshold was estimated by rule using an adaptive tracking technique that was developed from the modified International Standards Organization threshold-tracking procedures described by Harris (22).

The adaptive tracking technique used in threshold estimation required the subject to respond by pressing and releasing a button within specified time limits to indicate target onset and termination. Target onset was random, in a gaussian distribution with a mean of 2.8 seconds and a standard deviation of $\pm$0.8 seconds. Target-on time was slightly greater than 4 seconds. This duration provided listeners with at least one complete period of vital-signs signal. At the start of the trial, the level of the environmental sound in the room was automatically set to -16 dB from full-scale output[5]. The subject then heard the visceral sound, that was recorded through a specific stethoscope, when the environmental sound in the room was at that *same* sound intensity for a "familiarization" or pre-test listening period. Then adaptive tracking testing began, and the same visceral-sound was presented at that same level for a response in the appropriate recreated level of airborne environmental-noise. If undetected, the airborne level in the room was lowered 2 dB; if detected, it was raised an additional 2 dB and the appropriate stimulus presented from the matrix. As trials were presented, a change in performance from detection to failed detection, or its converse, was counted as a *reversal* in response. In all cases the vital-sounds signal presented at each trial was from the matrix previously recorded for that combination of device, and operational environment.

The dB value half-way between successive *reversals* during a trial was recorded as threshold. From this, the absolute value of that threshold's deviation from the trial accumulated *mean* threshold was derived. The sum of these absolute values was used to determine the average deviation (AD) which had to be 2 dB or less. At the end of 6 thresholds, if the value of the average deviation exceeded 2, additional thresholds were measured until 6 successive thresholds yielded an AD of 2 dB or less. Once this criterion was met, the averaged threshold and AD were recorded for the completed trial. If, after an additional 2 thresholds, the criterion was not met, testing was suspended and the subject re-instructed. A trial was also terminated and the subject re-instructed if the distance between successive reversals was greater than 10 dB.

LABORATORY EVALUATION RESULTS AND DISCUSSION

Data were subjected to a 3-way analysis of variance for repeated measures (29). As in any non-mixed repeated-measures design, *all* subjects were presented *all* conditions. As seen in Table 1, results showed a significant difference in the airborne levels at which the different stethoscopes could effectively present detectable vital-sounds (F = 72.5, *df* 6, 78). As expected the four different visceral sounds were significantly different in detectability (F =24.8, *df* 3, 39) as were the three environments (F =218.6, *df* 2, 26). All F values on these 3 main factors (device, vital sound, and environment) were significant beyond the .001 level.

Not surprising was a significant interaction between the various devices and the vital-sound to be detected (F = 13.1, *df* 18, 234), which was caused almost exclusively by the performance of the standard stethoscope. This interaction can be seen in Figure 1, which plots the detectability of

[5] Full scale output level in dB SPL was different for each of the environmental sounds. Calibration of the airborne level for each sound was done with the attenuator set to minimum attenuation (full gain). The starting point for testing was 16 dB below that level.

visceral sounds (as a function of the maximum level of device-tolerable[6] airborne noise), averaged across heart/lung sounds and noise environments, with the various stethoscopes. It is most important to note that with a conventional stethoscope detection of *abnormal* heart/breath is severely degraded by the noise environment. It is this difference in performance that is responsible for the significant interaction.

Table 1. **Results of 3-way repeated measures analysis of variance**

Source of Variation	*df*	SS	MS	F
Subjects	13	12519.000		
Vital-sound	3	7324.000	2441.333	24.840*
Error	39	3833.000	98.282	
Environment	2	14359.000	7179.500	218.580*
Error	26	854.000	32.846	
Device	6	13305.000	2217.500	72.492*
Error	78	2386.000	30.589	
Vital-sound x Environment	6	4217.000	702.833	21.085*
Error	78	2600.000	33.333	
Vital-sound x. Device	18	5680.000	315.555	13.183*
Error	234	5601.000	23.9359	
Environment x Device	12	1015.000	84.583	6.578*
Error	156	2006.000	12.859	
3-way Interaction	36	2197.000	61.027	4.652*
	468	6139.000	13.1175	

* significant - [p <.001]

There was a significant interaction between *environment* and the type of *visceral*-sound to be detected (F = 21.0, *df* 6,78). However, when the standard stethoscope is removed from the comparison, the only interaction remaining causes *abnormal* heart sounds to become slightly less detectable in the HumVee ambulance environment, than in the hospital field-generator environment. This can be seen in Figure 2, which depicts the mean detection and standard error for the various visceral sounds in different environments collapsed across *only* the six *experimental*-stethoscope conditions. This interaction, graphically seen as crossing plots between the Hum Vee and KW Generator is caused by the poor performance of the E-Scope stethoscope (3/3A) on *abnormal* heart sounds in the HumVee environment. Figure 5 depicts the poorer performance of the E-Scope stethoscope averaged across all of the tested visceral sounds. Though not shown as a figure, re-plotting Figure 2 with the E-Scope stethoscope (3/3A) removed, eliminates the plot-crossing in the heart-abnormal condition. A significant interaction between *device* and the *environment* in which the device was used is expected (F = 6.5, *df* 12, 156). The interaction between these three variables was also significant (F = 4.6, *df* 36, 468). All *F* values on these four interactions were significant beyond the .001 level.

Table 2, which lists the differences in detection performance in the three operational environments, shows that our selection of environments was well chosen. As seen by the 95% confidence intervals, the highest dB SPL values in which listeners could still detect the relevant

[6] Maximum airborne noise level at which the visceral sound could be detected using the device.

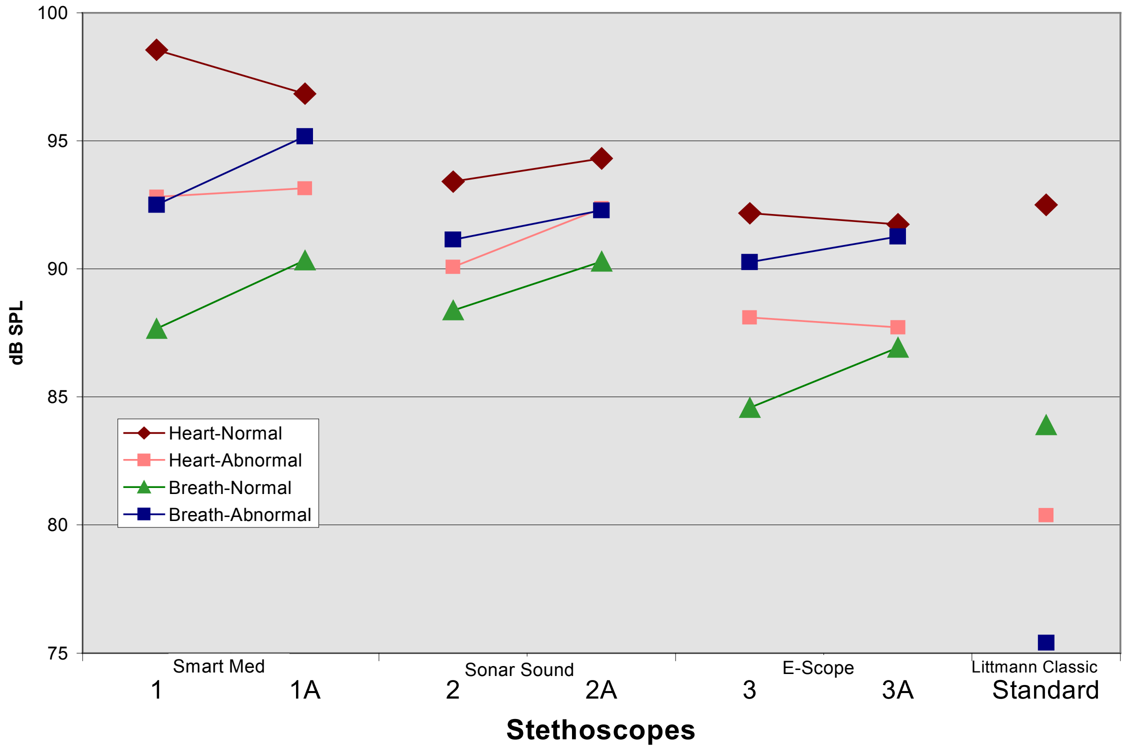

Figure 1. Detectability of visceral sounds with the 7 various stethoscopes

sounds were quite different. Detection of heart/lung sounds was hardest in the C-130 (84 to 88 dB SPL, ambient airborne noise), somewhat easier at the recommended distance from a field-hospital generator (88 to 92 dB SPL), and easier in a HumVee field-ambulance (92 to 96 dB SPL). Of course those values are averages for all vital-sounds tested and across all stethoscopes, including the standard device, to show the overall effect of *environmental* differences on detection[7].

Table 2. **Maximum detectability of heart/lung sounds in three different environments.**

Environment	Mean [dB SPL]	Std. Error [dB SPL]	95% Confidence Interval [dB SPL] Lower Bound	Upper Bound
KW Generator	90.2	.992	88.1	92.4
C-130	85.8	.929	83.7	87.8
HumVee	94.3	.882	92.4	96.2

Table 3 lists device performance averaged over all conditions. A Neuman Keuls test shows that for these 7 devices (n = 7, df 78), a critical value of greater than 5.51 is necessary for significance at the .05 level. Clearly, all 3 devices both as supplied, and with the added attenuation of the ANC headset, have averaged performance that is significantly better than the standard stethoscope. We cautiously limited the upper levels of noise exposure to safe limits based on duration and intensity. As a result, with some devices many listeners were still able to detect the visceral sounds at our highest levels. Unfortunately, we were only able to report their performance to that safe level. Our averaged results are therefore most likely conservative

[7] Figure 2 plots these same conditions, averaged with the standard stethoscope removed.

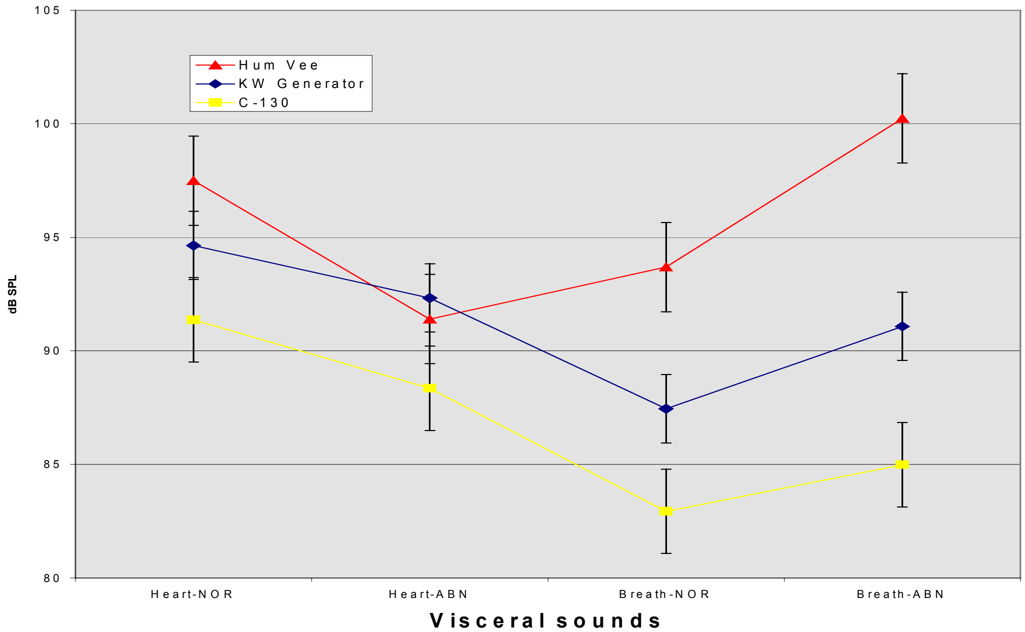

Figure 2. Detection of heart/lung sounds averaged across environments for six experimental stethoscope combinations.

(reduced) estimates of device performance. As far as the performance of the standard stethoscope, we positively biased its performance since, for a few subjects, an occasional inability to detect the vital-sound at the lowest level of presentation was estimated as a detection that would have occurred at the next lower level. Consequently, the difference estimates between our test devices and the normal stethoscope are most likely conservative. Also, note the tight 5 dB range of performance and operating-noise levels capable with the Smart Med and Sonar Sound devices. It compares favorably with the range of performance obtained using the standard stethoscope users were quite accustomed to.

Table 3. **Maximum detectability of heart/lung sounds across three environmental conditions**.

Stethoscope	Mean [dB SPL]	Std. Error [dB SPL]	95% Confidence Interval [dB SPL] Lower Bound	Upper Bound
1 Smart Med	92.8	.935	90.8	94.9
1A [1 with ANC]	93.8	1.087	91.5	96.2
2 Sonar Sound	90.7	.863	88.8	92.6
2A [2 with ANC]	92.3	.696	90.8	93.8
3 E scope	88.7	1.310	85.9	91.6
3A [3 with ANC]	89.4	1.049	87.1	91.6
Standard	**83.0**	**.849**	**81.2**	**84.8**

Figures 3, 4, and 5 depict individual device performance in detecting heart/lung sounds within the three operational environments of field-hospital generator (KWG), C-130 transport (C130) and field-ambulance (HUV) respectively. In these three figures the maximum airborne levels in which the heart/lung sounds could still be detected is shown. Note that in each of the three conditions the Smart Med would be the best overall choice and the E-Scope the poorest choice.

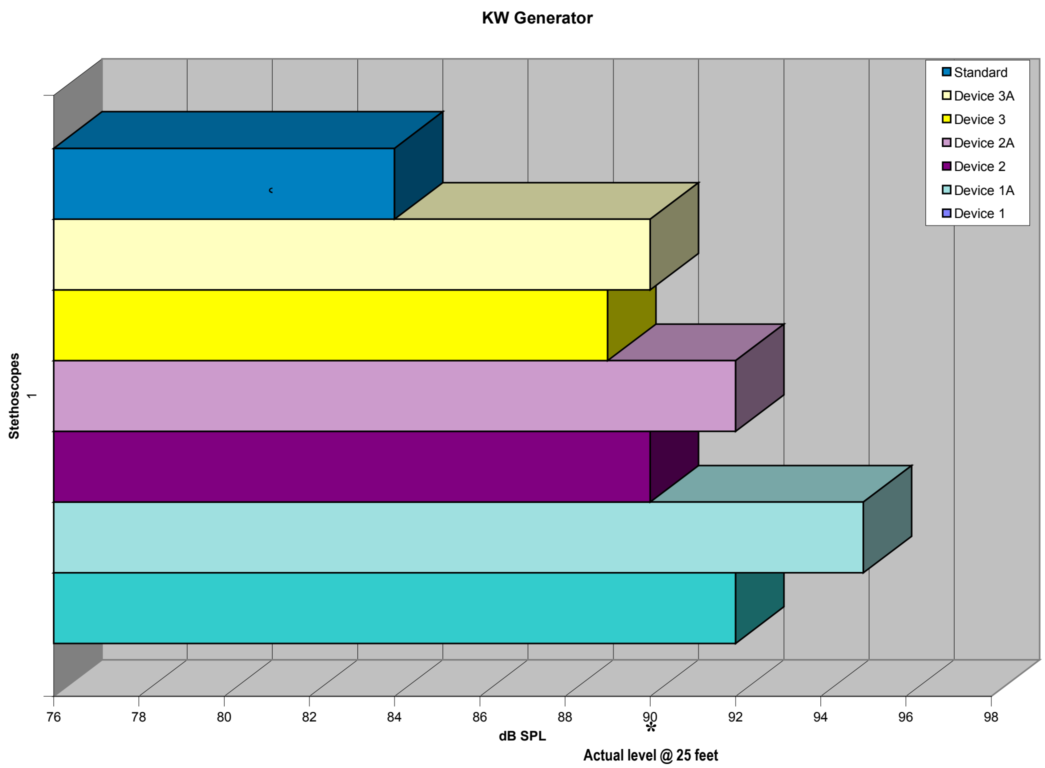

Figure 3. Individual device performance in the vicinity of a 100 KW generator for normal and abnormal heart/lung sounds. For comparison, actual field-measured levels were 90 dB SPL.

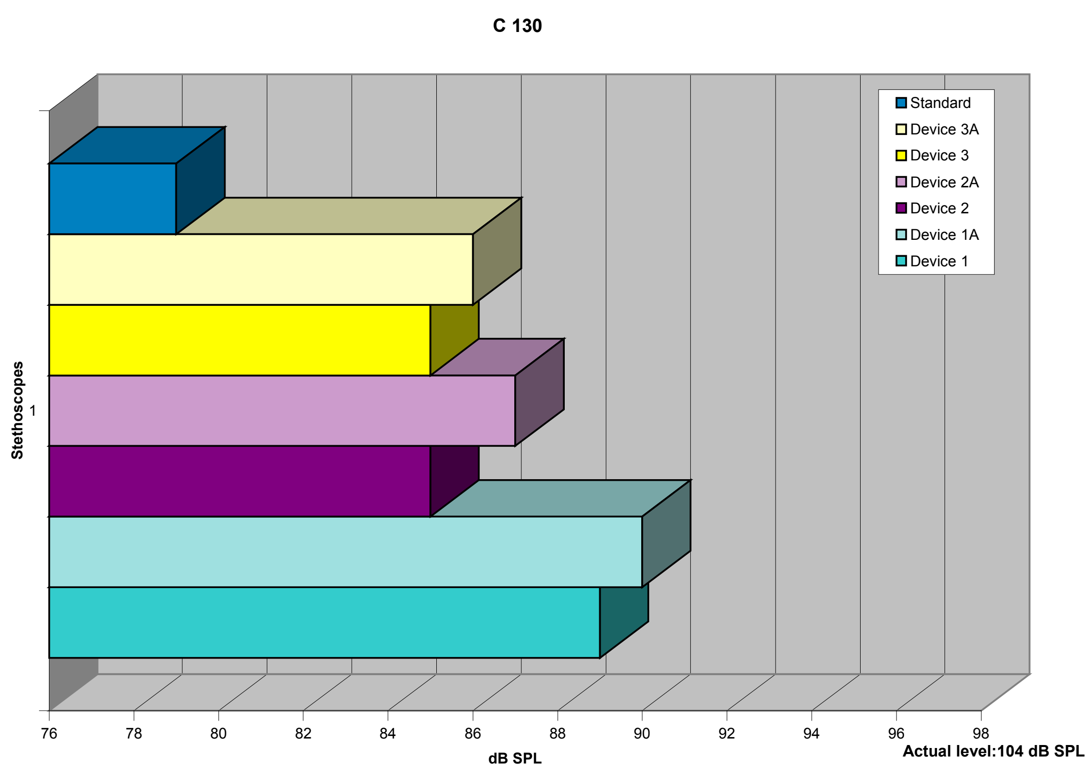

Figure 4. Individual device performance inside a C-130 transport for normal and abnormal heart/lung sounds. For comparison, actual field-measured levels were 104 dB SPL

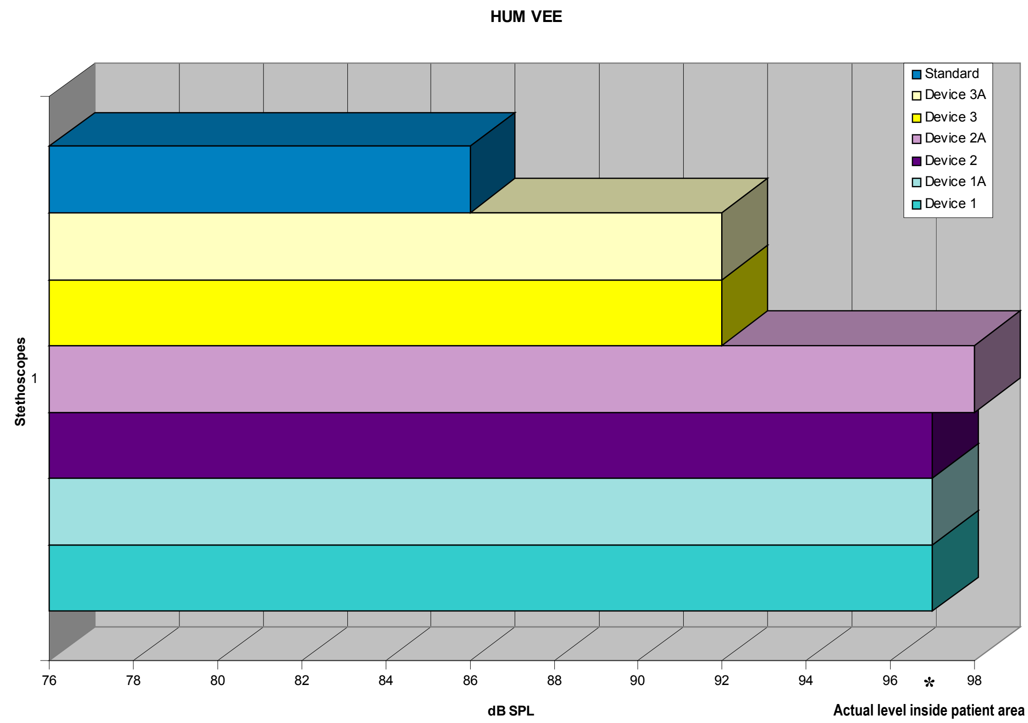

Figure 5. Individual device performance in a HumVee field-ambulance for normal and abnormal heart/lung sounds. For comparison, actual field-measured levels (97 dB SPL) are indicated.

Table 4. **Device performance in each environment.**

Environment	Stethoscope	Mean [dB SPL]	Std. Error [dB SPL]	95% Confidence Interval [dB SPL] Lower Bound	Upper Bound
KW Generator	1 Smart Med	92.2	1.082	89.9	94.5
	1A [1+ANC]	94.6	1.075	92.3	96.9
	2 Sonar Sound	90.1	1.143	87.6	92.6
	2A [2+ANC]	92.1	.954	90.0	94.1
	3 E Scope	89.2	1.311	86.3	92.0
	3A [3+ANC]	89.8	1.349	86.9	92.7
	Standard	**83.7**	**.856**	**81.8**	**85.5**
C-130	1 Smart Med	89.2	1.064	86.9	91.5
	1A [1+ANC]	89.9	1.350	87.0	92.8
	2 Sonar Sound	85.0	.838	83.2	86.8
	2A [2+ANC]	86.6	.682	85.1	88.1
	3 E Scope	84.6	1.356	81.7	87.5
	3A [3+ANC]	85.8	1.056	83.6	88.1
	Standard	**79.1**	**.946**	**77.0**	**81.1**
HumVee	1 Smart Med	97.1	.909	95.1	99.1
	1A [1+ANC]	96.9	1.289	94.1	99.7
	2 Sonar Sound	97.0	.870	95.1	98.9
	2A [2+ANC]	98.1	.676	96.7	99.6
	3 E Scope	92.4	1.441	89.3	95.5
	3A [3+ANC]	92.4	.990	90.3	94.6
	Standard	**86.2**	**.924**	**84.2**	**88.2**

Table 4 presents for each environment, the maximum dB SPL values, averaged across heart/lung sounds, at which listeners could detect the various vital-sounds. A critical value of 3.52 (Neuman Keuls $n = 7$, df 156) between devices is significant at the .05 level. These results show that, in the Hum Vee environment, though the E-Scope was able to function significantly better than the standard stethoscope, both the Smart Med and Sonar Sound devices were significantly better than the E-Scope in their tolerance to external noise. For the C-130 environment all three devices were significantly better than the standard. The E-scope and Sonar Sound were not significantly different from each other and the Smart Med was significantly better than all the rest. For the KW generator, the three non standard devices though not significantly different from one another were all significantly better than the standard stethoscope in their tolerance to airborne environmental noise.

Figures 6 and 7 depict, respectively, the detection *advantage* (or delta value) of Device 1, the Smart Med stethoscope, as supplied and when equipped with an ANC headphone, against a standard stethoscope. Both figures depict the average difference in intensity of operational-noise at which the tested devices allowed detection of the various vital-sounds. All 14 subjects heard all conditions using all seven possible listening conditions. The critical value necessary for a significant difference at the .05 level is 3.49 (Neuman Keuls $n = 7$, df 468). Non-significant differences are plotted in gray

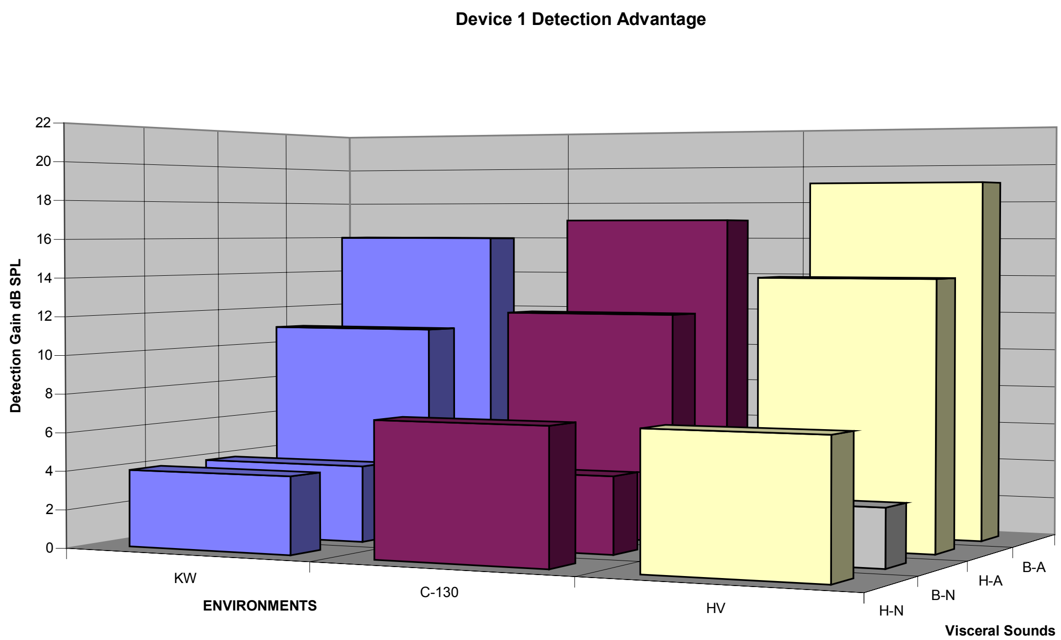

Figure 6. Device 1 (Smart Med) detection advantage over a standard stethoscope

Figures 8 and 9 depict, respectively, the detection *advantage* of Device 2, the Sonar Sound stethoscope, as supplied and when equipped with an ANC headphone, against a standard stethoscope. Both figures depict the average difference in intensity of operational noise at which the tested devices allowed detection of the various vital-sounds. The critical value necessary for a significant difference at the .05 level is 3.49 (Neuman Keuls $n = 7$, df 468).

Figures 10 and 11 depict, respectively, the detection *advantage* of Device 3, the E-Scope stethoscope, as supplied and when equipped with an ANC headphone, against a standard stethoscope. Both figures depict the average difference in intensity of operational noise at which

the tested devices allowed detection of the various vital-sounds. Again, the critical value necessary for a significant difference at the .05 level is 3.49 (Neuman Keuls $n = 7$, df 468).

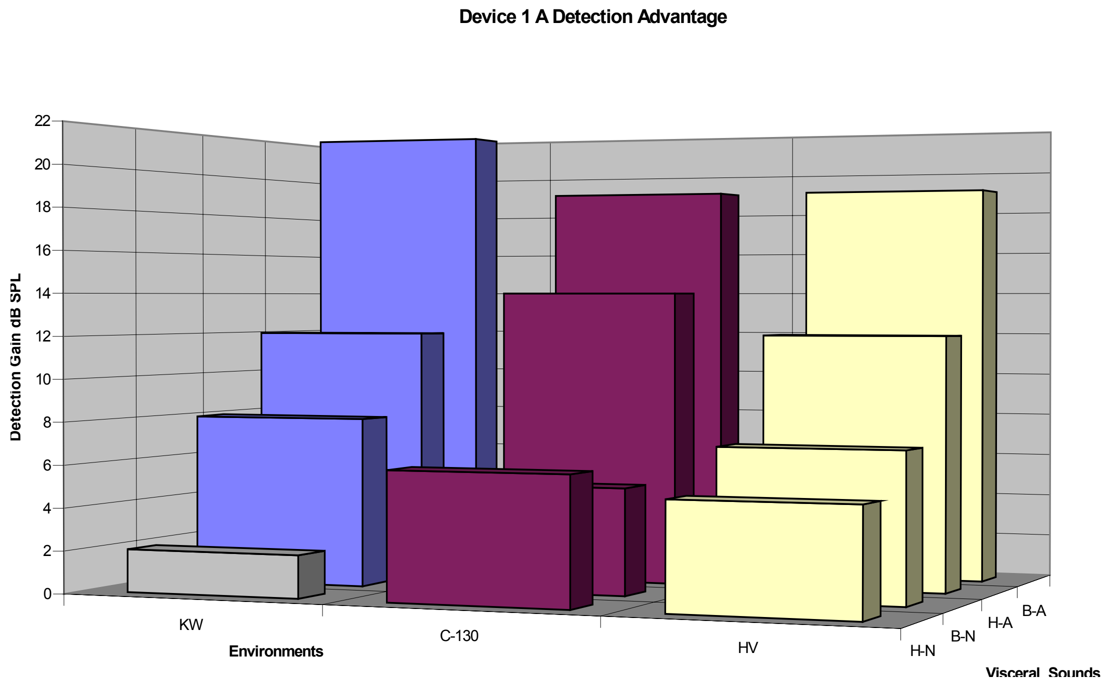

Figure 7. Device 1A (Smart Med/ANC) detection advantage over a standard stethoscope.

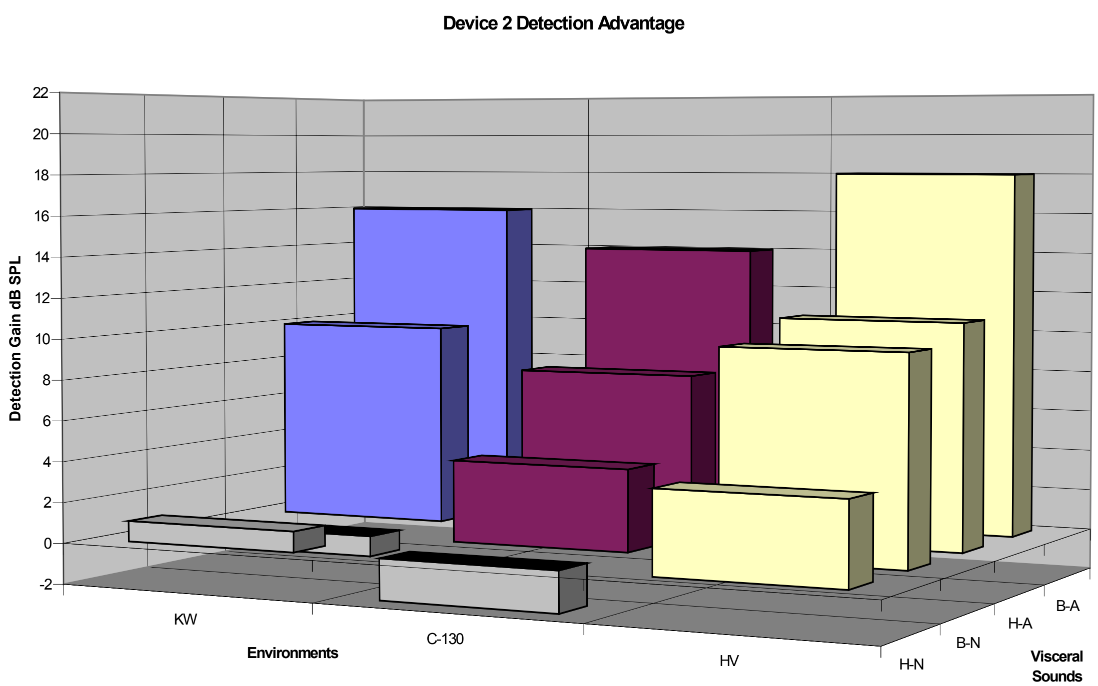

Figure 8. Device 2 (Sonar Sound) detection-advantage over a standard stethoscope.

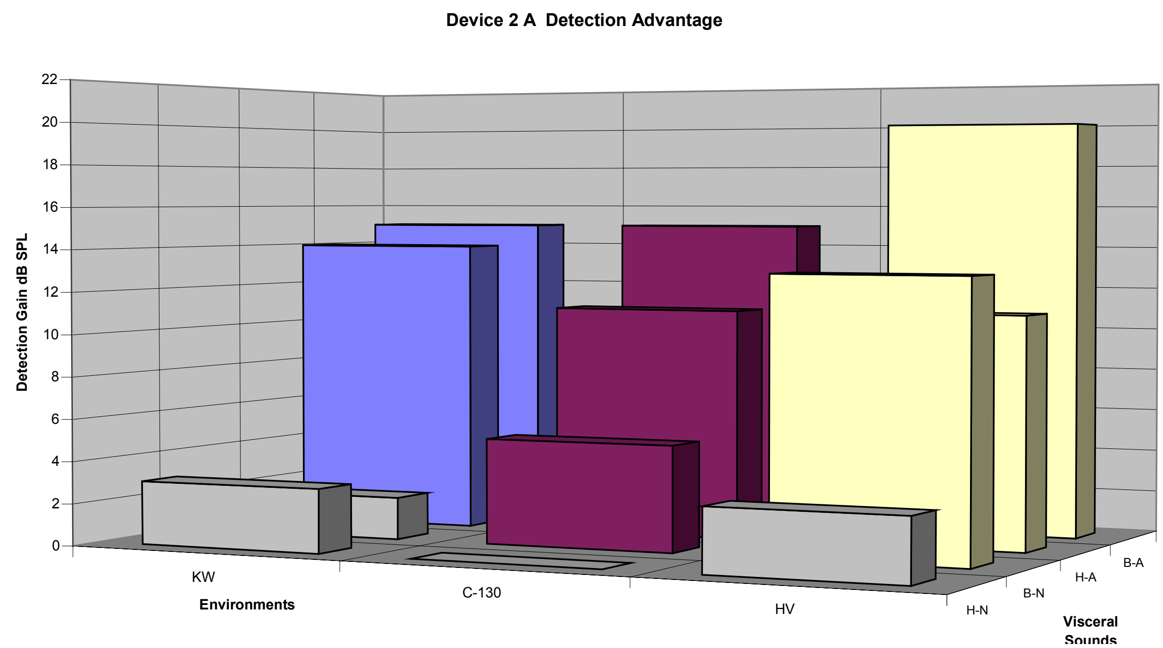

Figure 9. Device 2A (Sonar Sound/ANC) detection-advantage over a standard stethoscope.

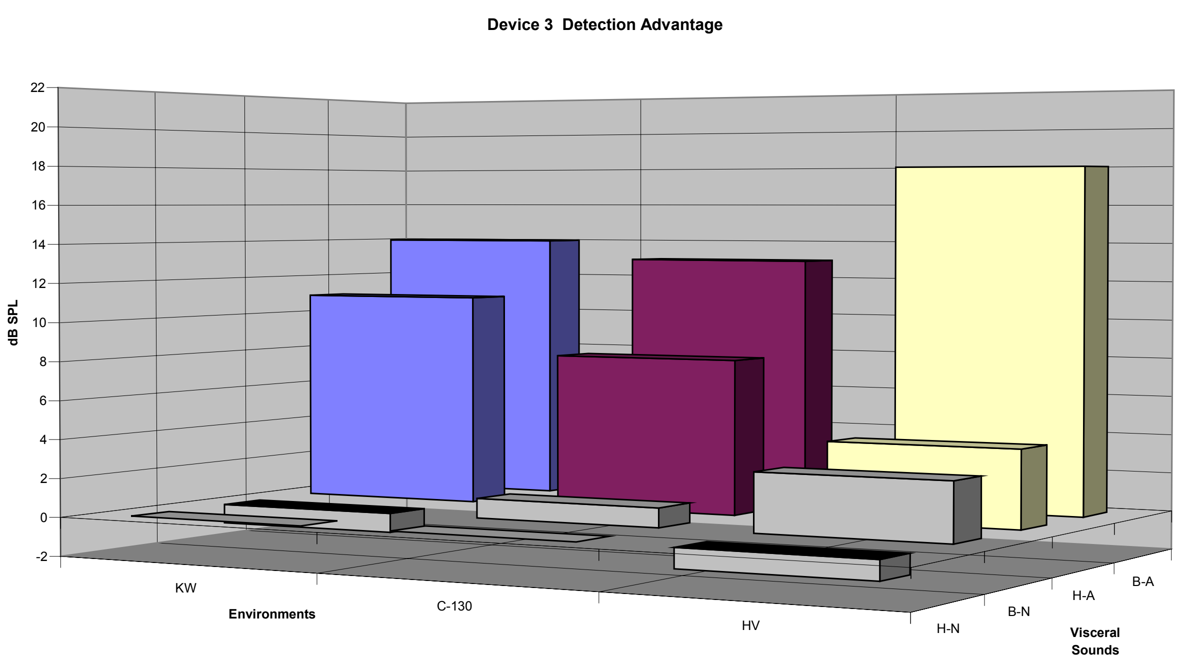

Figure 10. Device 3 (E-Scope) detection-advantage over a standard stethoscope.

Device 3A Detection Advantage

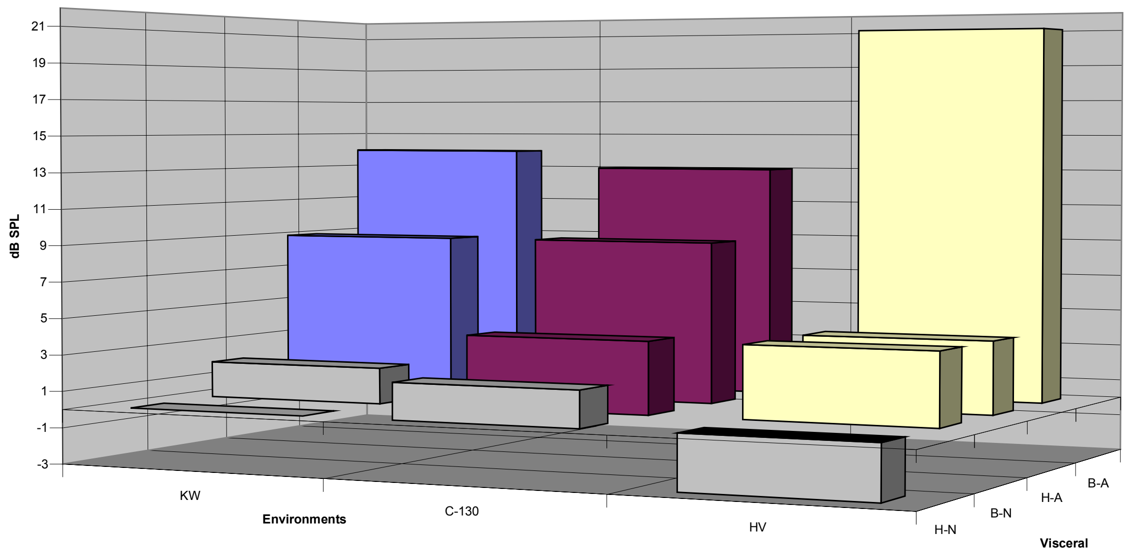

Figure 11. Device 3A (E-Scope/ANC) detection-advantage over a standard stethoscope.

To recap, in all four of the 3-dimensional representations depicted in Figures 6 through 11, those comparisons relative to a standard stethoscope that did not reach significance are shown in light gray. These comparisons are based on the averaged performance of all subjects. In no case did any of the devices perform significantly poorer than a standard stethoscope. Clearly, the greatest gains in audibility over a standard stethoscope are seen with *abnormal* breath (B-A) and *abnormal* heart (H-A) sounds, and those gains (8 dB to 22 dB) seen in Figures 6 through 9, are quite impressive for both the Smart Med and Sonar Sound devices even as supplied (8 dB to 19 dB). In fact, averaged across the three environmental conditions the detection gains achieved by the Smart Med stethoscope, when listening to *non*-normal sounds are 17.0 dB for breath and 12.4 dB for heart respectively. Under those same conditions, the Sonar Sound stethoscope exhibits a 15.8 dB gain for *abnormal*-breath and a 9.7 dB improvement for detection of *abnormal*-heart sounds, over the standard stethoscope.

Table 5 provides an operationally useful comparison among the various stethoscope configurations collapsed across conditions. Would the added audibility afforded from an ANC headset be worthwhile? As seen in Table 5, the 0.9 dB improvement gained with ANC for Smart Med stethoscope (1 /1A) is not significant. However, the 1.5 dB improvement obtained with ANC for the Sonar Sound stethoscope (2/2A) is a significant one. The gain might not be cost effective for general-issue, but it is available for specific applications where ANC headsets are already provided. For example, flight crew personnel commonly wear BOSE military ANC communications-headsets within their helmets, which are compatible with the outputs on these devices. In any decision, size is a most critical factor, and one that might exclude the use of Smart Med stethoscope over its 2dB less-noise-immune rival, the Sonar Sound stethoscope, which is significantly smaller. In comparison against the standard stethoscope Table 5 also shows that averaged across all conditions, Smart Med stethoscope produces an average 9.8 dB improvement over the standard stethoscope. Under those same conditions, Sonar Sound stethoscope produces a 7.7 dB improvement while E-Scope stethoscope produces a 5.7 dB improvement.

Table 5. **Pairwise comparisons of devices averaged across environments and heart/lung sounds.**

(I) Stethoscope	(J) Stethoscope	Mean Difference (I-J)	Std. Error	Significance level.	95% Confidence Interval for Difference [dB SPL]	
					Lower Bound	Upper Bound
1 Smart Med	1A [1+ANC]	**-.9**	.552	.097	-2.1	.2
	2 Sonar Sound	2.1	.516	.001	1.0	3.2
	2A [2+ANC]	.5	.551	.318	-.6	1.7
	E Scope	4.1	.643	.000	2.7	5.4
	3A [3+ANC]	3.4	.604	.000	2.1	4.7
	Standard	9.8	.778	.000	8.1	11.5
1A [1+ANC]	1Smart Med	.9	.552	.097	-.2	2.1
	2 Sonar Sound	3.1	.552	.000	1.9	4.3
	2A [2+ANC]	1.5	.509	.009	.4	2.6
	3 E-Scope	5.0	.690	.000	3.6	6.5
	3A [3+ANC]	4.4	.274	.000	3.8	5.0
	Standard	10.8	.693	.000	9.3	12.3
2 Sonar Sound	1Smart Med	**-2.1**	.516	.001	-3.2	-1.0
	1A [1+ANC]	-3.1	.552	.000	-4.3	-1.9
	2A [2+ANC]	-1.5	.335	.000	-2.2	-.8
	3 E-Scope	1.9	.585	.005	.7	3.2
	3A [3+ANC]	1.3	.437	.009	.3	2.2
	Standard	7.7	.631	.000	6.3	9.0
2A [2+ANC]	1Smart Med	-.5	.551	.318	-1.7	.6
	1A [1+ANC]	-1.5	.509	.009	-2.6	-.4
	2 Sonar Sound	1.5	.335	.000	.8	2.2
	3 E-Scope	3.5	.804	.001	1.8	5.2
	3A [3+ANC]	2.8	.425	.000	1.9	3.8
	Standard	9.2	.589	.000	7.9	10.5
3 E-Scope	1Smart Med	-4.1	.643	.000	-5.4	-2.7
	1A [1 +ANC]	-5.0	.690	.000	-6.5	-3.6
	2 Sonar Sound	-1.9	.585	.005	-3.2	-.7
	2A [2+ANC]	-3.5	.804	.001	-5.2	-1.8
	3A [3+ANC]	-.6	.653	.347	-2.0	.7
	Standard	5.7	.847	.000	3.8	7.5
3A [3+ANC]	1Smart Med	-3.4	.604	.000	-4.7	-2.1
	1A [1 +ANC]	-4.4	.274	.000	-5.0	-3.8
	2 Sonar Sound	-1.3	.437	.009	-2.2	-.39
	2A [2+ANC]	-2.8	.425	.000	-3.8	-1.9
	3 E-Scope	.6	.653	.347	-.7	2.0
	Standard	6.3	.659	.000	4.9	7.7
Standard	1Smart Med	**-9.8**	.778	.000	-11.5	-8.1
	1A [1 +ANC]	-10.8	.693	.000	-12.3	-9.3
	2 Sonar Sound	**-7.7**	.631	.000	-9.0	-6.3
	2A [2+ANC]	-9.2	.589	.000	-10.5	-7.9
	3 E-Scope	**-5.7**	.847	.000	-7.5	-3.8
	3A [3+ANC]	-6.36	.659	.000	-7.7	-4.9

Discussion

What is there about *abnormal* breath and heart sounds that makes them less detectable in noise using a standard stethoscope than any of the electronic versions? Clearly it is because they are fainter and therefore present a lower level at the ear. The *abnormal* breath sounds are shorter in duration and are more likely to have high-frequency energy that is attenuated by the transfer function of a standard acoustic stethoscope. Data on frequency response of conventional stethoscopes that show a 35 dB drop in output from 300 Hz to 3kHz (20, 21) would corroborate this. Apparently the electronic stethoscopes do not mimic the high-frequency attenuation characteristics of standard acoustic devices.

In Figure 1, the stellar performance of the Smart Med stethoscope (device 1) on normal heart sounds, which even exceeds that measured with the ANC headphones (device 1A), is primarily due to the exaggerated low-frequency response-characteristic of the Sony headset selected by the stethoscope manufacturer. Even at the highest levels of interfering noise, many reported "feeling" the heart-beat at the ear-drum. Despite noise-reduction advantages and a measured more accurate frequency response, the ANC headset did not elicit the same sensation. However a simple change in equalization in the active ANC headset electronics could duplicate the measured response of the Sony headset.

From Figure 5 we could see that the E-Scope stethoscope (3/3A) was not able to perform as well as the Smart Med stethoscope (1/1A) and the Sonar Sound stethoscope (2/2A) in the field-ambulance environment (about 5 dB poorer). The HumVee ambulance had a great deal of low frequency energy. Actual values recorded inside the patient area of a canvas-topped version transiting on flat terrain were 97 dB SPL. For the HumVee environment, the dBA weighting, which attenuates these lower frequency components, was 16 dB lower than the dB SPL values. Because the inclusion of an ANC headset with excellent low-frequency noise attenuation had no effect, we can safely conclude that, the E-Scope stethoscope does not attenuate lower frequencies of airborne sound as well as the other devices. That could account for the interaction it was found to cause, that was seen in Figure 2. Smart Med stethoscope and Sonar Sound stethoscope effectively extract the signal from the noise. The sensor-head on the Sonar Sound is apparently best at this, since with the added benefit of ANC, it improved further.

For the hospital field-generator, seen in Figure 3, it is apparent that each electronic device performs better with ANC, implying that the supplied headsets did not block the noise as well as the sensor-head made the signal available. Sound levels measured 25 feet from the 100 KW field-hospital power source were 90 dB SPL.

The C-130 environment was indeed the harshest, with a measured level of 104 dB SPL at the stretcher. In addition to a large noise component at lower frequencies, there is a large amount of energy in the 6 kHz region. As seen in Figure 4, each experimental device performs better, averaged across the visceral sounds, with the added noise reduction provided by the ANC headset. This implies, that in that noise environment, the supplied headset was unable to supply the information detected by the sensor.

The data make a strong point for the *cost-effectiveness* and *simplicity* of reducing *only* the airborne-noise that impinges on the stethoscope and on the listener's ears. During our laboratory data-collection we found that even slight *re-location* of the sensor-head had a major audible effect on the spectral characteristics of the noise picked up from within the torso. That is to say, using nomenclature from Zacharias *et al*. (16), noise N^p_2, the noise that has entered into the patient's body, is modified by the acoustic transfer characteristics of the torso, even with small changes in sensor position. When attempting techniques that use a separate skin mounted microphone, as a signal comparator, the requisite task of trying to model that location-specific transfer would seem a costly challenge. For whatever reason, all of the device manufacturers that exhibited proof of concept devices that attempted to reduce N^p_2 as well as those that attempted ANC technology at the sensor-head were unable to market a product during the course of our device testing.

Perhaps the strongest point to be made for the application of these noise reducing devices can be seen best in Figure 1 and in Figures 6-11. The fact that the *abnormal* visceral sounds were far more detectable using the noise-reducing devices makes a strong argument for using their listening advantage in health-emergency conditions.

Laboratory Evaluation
Conclusions

Under the well-controlled procedures of a repeated-measures test design, each stethoscope device was tested in a controlled noise environment as supplied, as well as with maximum attenuation of environmental noise at the ear using an ANC headset. Comparison allowed an evaluation of the intrinsic ability of the sensor and electronics to reduce environmental noise divested from any potential deficiencies caused by manufacturers' choice of listening device. Using digital storage techniques, listeners all heard the same visceral sound recorded earlier on a real patient using the device under test in a specific level of interfering environmental noise, with that same level accurately recreated around them. Performance biases potentially caused by the physical characteristics of the device were minimized, since only the device headset was provided to the listener during testing.

Laboratory results, best depicted in Figure 1, clearly indicate the numeric advantage of Smart Med and Sonar Sound devices over the standard stethoscope. But more important, they show that they really *excel* where it counts. They are exceptional in the detection of *abnormal* or faint visceral sounds more likely encountered in a real emergency environment. Figures 6 and 8 graphically show their detection advantage in detecting *abnormal* breath and *abnormal* heart sounds, compared to the standard stethoscope, in real-world interfering noise. Averaged across all conditions, Table 5 shows an *overall* detection advantage of 9.8 dB for Smart Med , and 7.7 dB for Sonar Sound over the standard stethoscope. However, for Smart Med , these gains dramatically improve to 17 dB for *abnormal* breath and 12.4 dB for *abnormal* heart sounds over the standard stethoscope. For Sonar Sound stethoscope, the gains are 15.8 dB for *abnormal* breath and 9.7 dB for detection of *abnormal* heart sounds.

PHASE 2: FIELD EVALUATION

METHOD

Subjects

All participants were informed volunteers. A total of 33 medical personnel were recruited, 13 members from the 156 Air Medical Squadron (C-130), 8 members from the USS John C. Stennis (CVN), and 12 members from the 1st Battalion 10th Marines supporting a Desert Combined Arms Exercise (CAX). No subjects withdrew from the study. Eighteen of the participants were enlisted personnel and 15 were officers.

Experimental Design

The data were collected from all three groups over a three-week period. Participants were asked to evaluate 4 types of stethoscopes: a Littmann conventional stethoscope and 3 noise reducing (NR) stethoscopes (SmartMed® (device 1); SonarSound™(device 2); and E-scope™(device 3). Prior to the evaluation period, participants were given instructions on how to use the stethoscopes and requested to perform auscultation tasks (heart sounds, lung sounds, and blood pressure) with each stethoscope during the evaluation period. Because of potential risks to *real* patients during field exercises, device-effectiveness in detection of *abnormal* heart and breath sounds could not be field-tested. Each participant had the opportunity to use the various stethoscopes on *healthy* war-fighters in noisy environments that were indicative of their normal working conditions (Table 6).

Table 6. **Environmental Areas used during the Stethoscope Field Evaluations**

GROUP	TESTING AREAS
C-130 156 Air Medical Squadron North Carolina Air National Guard Morris Field, Charlotte, NC	• On the flight line tarmac, while a C-130 engine was turning. • In the cargo hold area of the C-130 during flight.
CVN 74 USS John C. Stennis Naval Air Station North Island San Diego, CA	• On the flight deck (Vulture's Row and LSO platform) and in the Hanger Bay during flight operations. • In the primary Medical Spaces (Flight Deck Battle Dressing Station and Main Medical). • Engineering/Reactor spaces. • Berthing area passageway. • In a helicopter.
CAX 1st Battalion 10th Marines Camp Lejeune Jacksonville, NC On temporary assignment to the Combined Arms Exercise held at Twenty Nine Palms, CA	• On the M-16 Rifle Range. • In and near a field ambulance. • Near a running field generator. • Near a tank while the engines were running. • On the flight line tarmac, while helicopter engines were turning.

Evaluation Questionnaire

Upon completion of the field assessments, participants were asked to complete an evaluation questionnaire. The questionnaire was comprised of questions which fell into four primary categories: (a) duration of use, (b) design acceptance, (c) performance abilities, and (d) overall comments. As a result of comments made by the C-130 group, the first group to participate in the field trials, the questionnaire was modified to include blood pressure performance questions. A complete copy of the survey is included as ***Appendix C.***

For questions regarding design and performance aspects of the stethoscopes (questions 2 – 16), the participants rated how closely they agreed with each item by selecting one of five possible responses: "1" Strongly Agree; "2" Agree; "3" Undecided; "4" Disagree; or "5" Strongly Disagree. Participants were also asked to rank the stethoscopes according to the stethoscope's ability to perform certain functions (question 18.a – e) by selecting one of four possible responses: "1" representing the Best to "4" representing the Worst. Participants were given the opportunity to provide specific and general comments on each of the stethoscopes. Data from the questionnaires were entered into STATISTICA® for Windows, (StatSoft®, Inc.) and analyzed. Comments by the subjects are given in ***Appendix D***.

FIELD EVALUATION

RESULTS

Analysis

Descriptive analyses were performed for all questions. Results are presented as means ± S.D.[8]. The criteria for significance were determined a priori at $p < 0.05$. Each question was analyzed using a split-plot repeated measures analysis of variance (29) ("groups" as the independent variable and "stethoscopes" as the dependent variable), followed by a Tukey's HSD post hoc test. Differences between group and ultimate choice were analyzed using Chi-square. Questions that requested a written response were reviewed and the frequency recorded by the primary field-investigator.

Results

(1) Usage and Design: As shown in Table 7, the stethoscopes each received a *usage* response of 2 indicating that all were used 1-5 times by each participant. The overall *head/sensor design* on each of the stethoscopes was found to be acceptable by all the groups in terms of *ease of placement* on the patient. However, the C-130 group agreed significantly more ($p<.01$) than the CVN group regarding placement ease. Compared to the conventional ($p<.01$) or E-Scope ($p<.01$) design, the head/sensor on the Sonar Sound was slightly harder to place on the patient. The conventional head style was easier to stabilize compared to the Sonar Sound ($p<.05$) and SmartMed ($p<.01$) design. The CAX group found the head/sensors on the Sonar Sound ($p<.02$) and conventional ($p<.02$) stethoscopes were slightly more comfortable than on the SmartMed. Comments from the participants indicated that the SmartMed head/sensor was big and bulky and that Sonar Sound produced excessive background noise when the head/sensor was moved from area to area on the chest.

The participants agreed that the *cable lengths* and *the earpiece/headsets* were adequate for all the models. The location of the control box relative to the listener was also found to be acceptable, however there was a slight variation in the strength of this agreement relative to the stethoscopes, which was not further defined after performing a post hoc test. The size of the SmartMed control box[9] was unacceptable compared to the others ($p<.01$) and was found to be slightly harder to operate than the E-Scope ($p<.04$) model. The control buttons on the SmartMed were also slightly harder to reach than on the Sonar Sound model ($p<.05$). Compared to the E-Scope model, the control buttons on the Sonar Sound ($p<.03$) were slightly easier to see.

Although the overall layout of the stethoscope models were adequate, the conventional stethoscope was considered more adequate than the SmartMed ($p<.02$) or Sonar Sound ($p<.05$) designs.

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[8] Standard Deviation

[9] Box size has been reduced to 46% of original size in newest production model.

Table 7. **Usage and Design: Evaluation Questionnaire**

	Significant Difference	**Mean**	**S.D.**
I. USAGE**:**			
1. Indicate the number of times you used each stethoscope (i.e. number of patients) **(1: None 2: 1-5 times)**:			
[1] Smart Med:		2.00	0.25
[2] Sonar Sound:		2.00	0.26
[3] E-Scope:		2.03	0.17
II. DESIGN: **(1: Strongly Agree 2: Agree 3: Undecided 4: Disagree 5: Strongly Disagree)**			
2. Head/Sensor is easy to place on the patient:	**		
[1] Smart Med:		1.81	0.69
[2] Sonar Sound:		2.03	0.94
[3] E-Scope		1.69	0.64
Conventional:		1.47	0.51
3. Head/sensor is easy to stabilize (keep from moving):	**		
[1] Smart Med:		2.09	0.93
[2] Sonar Sound:		1.86	0.79
[3] E-Scope:		1.72	0.63
Conventional:		1.40	0.50
4. Head/sensor fits comfortably in the hand:	**		
[1] Smart Med:		2.13	1.06
[2] Sonar Sound:		1.63	0.89
[3] E-Scope		1.69	0.59
Conventional:		1.47	0.51
5. Cable/hose length from the head/sensor to the control box is adequate:			
[1] Smart Med:		2.03	0.82
[2] Sonar Sound:		1.97	0.73
[3] E-Scope:		2.06	1.01
6.Control Box is easy to operate:	**		
[1] Smart Med:		2.56	1.16
[2] Sonar Sound		2.17	0.87
[3] E-Scope:		2.06	0.80
7. The size of the control box is acceptable:	**		
[1] Smart Med:		4.00	0.88
[2] Sonar Sound:		2.53	1.22
[3] E-Scope:		2.25	1.02
8. Control buttons are easy to reach:	**		
[1] Smart Med:		2.47	1.05
[2] Sonar Sound:		2.13	0.73
[3] E-Scope:		2.16	0.68
9. Control box is conveniently located on the listener:	**		
[1] Smart Med:		2.94	1.19
[2] Sonar Sound:		2.37	0.89
[3] E-Scope:		2.44	0.91
10. Control buttons are easy to see:	**		
[1] Smart Med:		2.19	0.86
[2] Sonar Sound:		2.10	0.61
[3] E-Scope:		2.56	0.95
11. Ear piece/headset is comfortable:			
[1] Smart Med:		1.94	1.01
[2] Sonar Sound:		2.23	0.90
[3] E-Scope:		2.23	0.92
Conventional		1.95	0.78
12. Cable length from the ear piece/headset to the control box is acceptable:			
[1] Smart Med:		2.23	0.80
[2] Sonar Sound:		2.17	0.66
[3] E-Scope:		2.19	0.83
13. The overall layout (control box, head, earphones) of the stethoscope is adequate:	**		
[1] Smart Med:		2.81	1.03
[2] Sonar Sound:		2.33	0.84
[3] E-Scope:		2.31	0.90
Conventional		1.85	0.75

**$p<0.05$ for stethoscope effect

Table 8. **Performance: Evaluation Questionnaire**

III. PERFORMANCE:

(1: Strongly Agree 2: Agree 3: Undecided 4: Disagree 5: Strongly Disagree)

		Total		C-130		CVN		CAX	
		Mean	S.D.	Mean	S.D.	Mean	S.D.	Mean	S.D.
14.	Stethoscope improves ability to hear heart and lung sounds in a noisy environment:			N/A	N/A				
	[1] SmartMed:	2.37	1.12			3.00	1.41	1.91	0.54
	[2] Sonar Sound:	3.00	1.37			3.88	1.55	2.30	0.67
	[3] E-Scope:	2.68	1.42			3.13	1.55	2.36	1.29
	Conventional:	2.94	1.21			2.43	0.79	3.27	1.35
15.	Stethoscope improves ability to determine blood pressure in a noisy environment:			N/A	N/A				
	[1] SmartMed:	2.25	0.97			2.75	1.04	1.92	0.79
	[2] Sonar Sound:	2.39	1.04			2.38	1.06	2.40	1.07
	[3] E-Scope:	2.60	1.10			2.75	1.04	2.50	1.17
	Conventional:	2.65	1.09			2.63	0.74	2.67	1.30
16.	Stethoscope would improve the quality of patient care in a noisy environment:			*				*	
	[1] SmartMed:	2.94	1.32	3.58	1.38	2.88	0.99	2.33	1.23
	[2] Sonar Sound:	2.60	1.13	2.83	1.40	2.75	1.16	2.20	0.63
	[3] E-Scope:	3.13	1.34	3.92	1.16	2.63	1.19	2.67	1.30
	Conventional:	2.85	0.99			2.50	0.53	3.08	1.16
17.	In a noisy environment, I would choose to use this stethoscope (group percentage):			N/A	N/A				
	[1] SmartMed:	15%				0%		25%	
	[2] Sonar Sound:	20%				25%		17%	
	[3] E-Scope:	35%				25%		42%	
	Conventional:	30%				50%		17%	
17a.	Compared to the Conventional, it improves my ability to hear heart and lung sounds in noise:					N/A		N/A	
	[1] SmartMed:			3.91	0.83				
	[2] Sonar Sound:			2.82**	1.08				
	[3] E-Scope:			4.09	0.83				

*** p < 0.05 for group effect**
**** p < 0.05 for stethoscope effect**

N/A - Not applicable; these questions were not addressed to these subject groups.

(2) Performance: As shown in Table 8, the CAX group agreed that the electronic stethoscope models improved their ability to determine blood pressure and hear heart and lung sounds in a noisy environment. The C-130 group were given an earlier questionnaire that posed this question slightly differently asking them to compare NR stethoscope performance against a conventional stethoscope. For that reason their response to that question is not included in Table 8. In response to that question, compared to a conventional stethoscope, the C-130 group agreed the Sonar Sound (2.91 $\pm$ 1.22; p<.01) model improved their ability to hear normal heart and lung sounds, while the E-Scope (4.45 $\pm$ 0.69) and SmartMed (4.18 $\pm$ 0.98) models did not improve their ability. Overall, the participants were undecided on whether the stethoscopes would improve the quality of patient care in a noisy environment, with the C-130 group responding a little more strongly that the models may not improve patient care (p<.01) than the CAX group.

With regard to specific performance factors, the participants ranked the conventional stethoscope (p<.01) as being the easiest model to use compared to the SmartMed model. For the ability to reduce noise, the C-130 (p<.04) and CAX (p<.02) groups ranked the conventional stethoscope much worse than the CVN group. When compared to the C-130 group, the CVN and CAX groups tended to rate the NR stethoscopes as being slightly better in their ability to hear heart and lung sounds. Compared to the conventional Stethoscope, the SmartMed model was

considered to be better for hearing heart sounds ($p<.02$) and the E-Scope model was better for hearing lung sounds ($p<.03$).

For the CVN and CAX participants, when asked which stethoscope they would choose to use in a noisy environment, the choice frequency was: 15% for SmartMed, 20% for Sonar Sound, 30% for the conventional and 35% for E-Scope. The C-130 group indicated they would prefer to use the Sonar Sound model instead of the conventional stethoscope.

FIELD-TEST CONCLUSIONS

The primary purpose in conducting the field trial study was to assess some of the operational capabilities and limitations associated with the various noise-reducing (NR) stethoscopes. Thus, the *primary* focus of the questionnaire was on factors related to design, performance, and operational acceptability. The data from the operational testing needs to be interpreted in a conservative fashion. While many of the comparisons between the various subject groups and stethoscope models were statistically significant, it should be noted that this study was limited by:

1) The inability to evaluate *abnormal* heart and breath sounds in field-operation conditions, because of potential human risks to *real* patients during the operational exercise. This is most relevant since, analysis of the laboratory data makes it clear that it is *exactly* in these more-critical listening tasks that these products dramatically outperform the standard stethoscope.
2) The *novelty* of the devices compared to the use-experience of a standard stethoscope
3) The inability to *control* and *limit* the sound-levels on which subjects based their evaluations. Our subjects insisted on trying the devices in noise levels beyond their design limit.
4) The incapability to *standardize* the types of sound environments and *levels* of the visceral sounds experienced by each of the subjects as they evaluated the stethoscopes during actual field operations.
5) A small *sample size* within each group

Within those limitations, the field preference-data appropriately do not support the assumption that a single NR stethoscope model could accommodate the medical needs of all the groups in *all* military field-environments where some noise levels can easily exceed 120 dB SPL. Keep in mind that the design goal was for a *small, simple, general-issue* device that would function at levels under 90 dB SPL over a device, yet to be built, that can remove structural vibration transmitted into the torso. With regard to the overall design of the stethoscopes, the groups were in agreement that the conventional stethoscope was the most adequate design. However, they preferred the small compact size of the E-Scope stethoscope with its integral control box, and the push-button style membrane switch associated with the Sonar Sound stethoscope. Other factors will be addressed separately for each group.

C-130 Group: During the evaluation period, the C-130 group was almost constantly exposed to an extremely high noise environment (greater than 100 dBA), especially during the flight operations. Within this environment, the participants were unable to detect even *normal* heart or lung sounds with any of the stethoscopes since it was well out of the intended operating range of these compact devices. Several participants mentioned they were able to detect blood pressure

with the Sonar Sound stethoscope while in flight, which could be considered an operational benefit. The participants currently rely on the palpation method for patient evaluation during flight and would prefer a more accurate way of monitoring the patient. Although automatic blood pressure devices are available that do not rely on acoustic input for measurements, several devices would be needed to accommodate the large number of patients that can be transported aboard the C-130, thus making the purchase of those machines cost prohibitive. Some participants mentioned that it would be a benefit if the headset/earpiece could be incorporated into their flight communication headsets to prevent any unprotected exposure to the C-130 noise level. In fact *all* of the tested devices can easily be patched into their flight helmet ANC headsets.

The participants also evaluated the stethoscopes at a staging-area located directly behind the C-130. This is an area where final patient evaluation may occur before the aircraft takes off. The sound level in this area is approximately around 70 – 80 dBA. The participants found that the Sonar Sound stethoscope performed better than the other stethoscopes for detecting blood pressure and for hearing *normal* heart and lung sounds. Overall, the C-130 group indicated that the Sonar Sound stethoscope could potentially improve their patient care abilities.

CVN Group: In the general comment section of the questionnaire, a corpsman aboard the USS John C. Stennis reported:

> "In most cases a patient on the flight deck who is thought to have an injury which must be further assessed with a stethoscope will be taken to Main Medical within minutes. The environment is too loud and hazardous to keep a patient there, for long. Generally we assess airway, c-spine, breathing, and circulation, put the patient on a stretcher and have them in Main Medical in about 2-8 minutes post the time of injury."

As demonstrated by this statement, the medical personnel aboard an aircraft carrier rarely perform medical procedures in extremely high noise environments (greater than 100 dBA), such as the Flight Deck, Hanger Bay, or Engineering Spaces. These areas are considered unsafe for both the patient and medical personnel, so procedures have been developed to move the patient safely away from the noisy environment to a safer area. The noise around the safer areas would probably be around 80-84 dBA. Within these areas, the participants found that, for *normal* healthy patients, the NR stethoscopes performed only slightly better than the conventional stethoscope. Since the conventional stethoscope performed adequately in the slightly noisy areas, 50% of the participants indicated that they would choose the conventional stethoscope over the NR stethoscope models. Again, keep in mind they were never given the opportunity to evaluate a faint or abnormal visceral sound in their evaluation. Participants also indicated that often times they use their own personal conventional stethoscope (i.e. Littmann Cardio II), which is slightly better than the government issued item. In fact this is the model we used as the conventional device in our laboratory tests, to afford our listeners the best possible acoustic stethoscope for their comparisons. The laboratory results for the Littman seen in Figure 1 corroborate their field findings on detection of normal healthy heart and breath sounds.

The Navy is currently researching the possibility of incorporating telemedicine technology as part of the shipboard medical capabilities. The ability to interface a stethoscope with the telemedicine system would be an operational asset to the medical facility. The conventional stethoscope does not have Telemedicine capability, however the NR stethoscopes are able to link with computer systems and provide the advantage of noise reduction as well.

CAX Group: Similar to the CVN group, the participants within this group were exposed to a wide range of noise levels and they had also developed procedures to remove patients from the high noise environments when possible. For the field trials, most of the participants evaluated the stethoscopes in high and moderately-high noise environments (between 85 to 100 dBA), such as those found near field generators, truck engines, and artillery fire.

General comments indicate that *size*, *simplicity*, and *durability* were the main factors that influenced a number of their responses. Forty-two percent of the participants said they would choose the E-Scope stethoscope over the others, though laboratory data show this device to be the least effective of the three. This apparent selection bias was likely due to E-Scope stethoscope's small, compact, and easy to use, design. From their operational point of view, the stethoscope needs to be small enough to fit within their medical packs. Although it is similar in size to E-Scope stethoscope, only 17% said they would choose Sonar Sound stethoscope. Concern was expressed that the removable cable connection between the head and the control box may be a durability and safety concern. Subsequent to their evaluation the Sonar Sound stethoscope has been modified as prototype 2 seen in ***Appendix E***. The head is no longer removable from the cable.

With regard to performance capabilities with *healthy* patients, the participants ranked the E-Scope stethoscope better than the conventional stethoscope for ability to reduce noise, detect blood pressure, and improve the ability to hear *normal* healthy heart and lung sounds. Similar to E-Scope stethoscope, Smart Med stethoscope was also considered the best for hearing heart sounds; however only 25% of the participants would choose Smart Med stethoscope, mainly because of the large control box size. Participants mentioned in their comments that they would have considered Smart Med stethoscope if it were smaller and more compact. Subsequent to their evaluation, Smart Med stethoscope *has* been reduced in size by 46% (prototype1, ***Appendix E***). Since Smart Med stethoscope has a headset design as opposed to an earpiece design, concern was raised that the corpsmen would need to remove their flak helmets in order to assess patients, which in a combat situation could be an operational hazard.

As mentioned in the CVN group, Smart Med stethoscope costs more than E-Scope stethoscope and significantly more than the conventional stethoscope, which makes this option a strong cost consideration for this group (and needlessly biases their selection if the item were general issue). However, the potential for telemedicine is also an important factor. As discussed earlier, the NR stethoscopes evaluated were selected for their ability to connect with various telemedicine systems, including systems located on laptop and mini-laptop computers. This capability would provide a greater communication link between the field corpsmen, the Battle Aid Stations, the Field Hospitals, and the main medical facilities.

Final Recommendations Based on Field Trials With Normal Heart And Breath Sounds: In general, the evaluation survey revealed advantages and limitations for the three NR stethoscopes, which were dependent upon the type and level of noise environment used during the evaluation. Based on factors related to design, performance, cost, and operational acceptability, the following recommendations can be made as to preference for or against the standard stethoscope:

C-130 Group**:** Sonar Sound stethoscope, because of its ability to detect blood-pressure while in flight and improve ability to hear heart and lung sounds while on the flight line.

***CVN Group*:** Sonar Sound stethoscope or E-Scope stethoscope, because these smaller models will allow for telemedicine capabilities and will improve ability to hear heart and lung sounds in moderately noisy shipboard areas.

***CAX Group*:** E-Scope stethoscope, because it's small, compact, and is easy to use. It also has the ability to reduce noise, detect blood pressure, and improve the ability to hear heart and lung sounds. However, Smart Med stethoscope may be a better choice if design modifications could be made to reduce the size of the box and the head/sensor and replace the headset with an earpiece design. [Subsequent to the field tests the newest production model of this device has been reduced in size by nearly 46% which is a major reduction in size. See Appendix E: production-prototype 1.] This significant improvement in functionality would also be relevant to the sized related selection criteria manifest by the CVN group.

SUMMARY & CONCLUSIONS

LABORATORY & FIELD-TESTING

The present study has provided an evaluation of several small COTS noise-reduction stethoscopes capable of exceptional performance in *moderately-intense* noise, which can be used stand-alone by medics in the battlefield, but also can function as a key component in electronic data gathering. These products allowed trained medical personnel to detect heart/breath sounds in noise environments significantly louder than possible when using a conventional stethoscope. Because each is relatively inexpensive, (less than $500 in single quantities), mass distribution is possible. Once a general-issue item, familiarity with its use and placement should enhance performance beyond our limited-experience comparisons made against a highly familiar stethoscope device. Since each was selected to have an electrical output, with available software it can serve as the ideal front-end acoustic sensor for medical diagnostics within the rapidly developing field of ultra-miniaturized COTS Pentium devices. As a *modular,* rather than totally integrated component, it is less likely to obsolescence in such a rapid evolution in processor hardware and software. It is in this *modular* application that the *easily-operated general-issue* (therefore familiar) noise-reducing stethoscope device becomes *essential*.

Each stethoscope device was laboratory-tested in a controlled-noise environment both as supplied, and with maximum attenuation of environmental noise at the ear. Comparison allowed an evaluation of the intrinsic ability of the sensor and electronics to reduce environmental noise divested from any potential deficiencies caused by manufacturers' choice of listening device. Using digital storage techniques, listeners all heard the same visceral sound recorded earlier on a real patient using each device in a range of levels of interfering environmental noise, with that same level accurately recreated around them.

Laboratory Findings

Laboratory data show that for the SmartMed® stethoscope, performance improvement, averaged over the three environments, is 17 dB for *abnormal* breath sound and 12.4 dB for *abnormal* heart sound. For the Sonar Sound™ stethoscope, performance improvement for these same *abnormal* sounds is 15.8 and 9.7 dB respectively. These performance improvements are, of course, gains in detectability over a standard stethoscope. Of far more relevance, they allow trained medical personnel the ability to hear medically relevant *abnormal* visceral sounds in the region from 85 to 95 dB SPL, a region well out of the listening range afforded by even the best

conventional stethoscope. Laboratory data also show that while normal *healthy* heart sounds can be heard with a conventional stethoscope in a fairly loud environment, abnormal or *weak* visceral sounds cannot.

Field Test Caveats:

The field-testing must be viewed in perspective. We field-evaluated the three COTS devices over a range of simulated combat situations that in most cases *far* exceeded our operating criterion of 90 dB SPL[10]; environments where little design effort was taken to reduce the structurally transmitted components of energy that entered the torso. Basically our test volunteers wanted to see exactly what these devices could do across the full range of combat environments *without* regard to their design operating limits. While it was useful to check their potential in this environment, inclusion of these excessive conditions did *bias* these field-test listeners by trying to use the devices in airborne and structurally transmitted noise environments beyond their intended operating range. Sound pressure levels in the C-130 were 14 dB higher than the intended design-operating range of the *miniature* field-device. However, the field tests were able to demonstrate that the Sonar Sound device was extremely useful in detecting blood pressure in the 104 dB SPL environment of a C-130. Most relevant to interpreting the field-reports is the fact that, because of our concern for the safety of patients with *abnormal* vital signs, detection of *abnormal* heart and lung sounds were *not* evaluated in field-exercise testing. Analysis of the laboratory data makes it clear that it is *exactly* in these more-critical listening tasks that these products dramatically *outperform* the standard stethoscope. For that reason the field data are most appropriately used to assess users' comments on questions 1-13 (***Appendix C***). The field-users had no way of assessing how much better these devices worked on *abnormal* visceral sounds, and during their volunteer field-test efforts they used them in environments well beyond their intended operating level. As a result their responses to questions 14 through 17a (***Appendix C***) are *not* an accurate assessment of the improved capability of the device within its intended sound-level design limits in *true* medical trauma. The laboratory-data seen in Figure 1 clearly confirm this. Based on the ability to detect normal heart sounds from a *healthy* young adult male, the added cost of these stethoscopes would not be warranted. However in emergency situations, *abnormal* or *faint* heart and breath sounds are quite relevant, and here the performance of these devices is exceptional.

Field Findings

Perhaps the most important fact that the field data show is that users will sacrifice *performance* for *size* and *familiarity*. No matter how well they perform over the conventional, *novel* devices of any type require more than a few hours use to become second nature. They require different handling and methods of stowage that need to become "routine." For that familiarity to occur rapidly, they need to be intuitively simple for the user to deploy and operate.

Our Recommendation

It is our recommendation that the two noise- reduction stethoscopes mentioned below, and specified in ***Appendix F***, be issued into the federal stock system for *immediate* use in the far-more commonly encountered *moderately-loud* (70-90 dB SPL) noise environments. With those specifications the devices can be competed under bid. While these are currently COTS devices, with large purchases ruggedization for specific extreme application is always possible. For use under *extreme* battlefield conditions we recommend further ruggedization of any COTS device.

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[10] Actual measured levels of the environments:

100 KW Generator @ recommended 25 feet	90 dB SPL
Hum Vee (patient area during soft-sand transit)	97 dB SPL
C-130 (patient area during level flight)	104 dB SPL

Along with that general-issue recommendation is the recommendation that users be given training in their significant capability in noisy environments and training to understand those limitations based on *size* and *cost* that specifically limits use to *exclude* intense noise levels (above 90 dB SPL). Usually such environments, as in military helicopters, are contaminated by structurally-transmitted noise that these small field-pack devices are not designed to handle. Users must also be instructed to understand that, in noise areas above 90 dB SPL, with continuous exposure without the additional protection of ANC headsets (such as in aviation flight-helmets), they are exposing themselves to risk. The standard noise exposure instructions outlined in OPNAVINST 5100.23E (see their Appendix 18-C) apply (30).

It is also our recommendation that these small devices be used for their ability to provide the best possible electrical signal for telemetry and also to any of the various software programs that allow acoustic records of patient pathology[11].

Once a general-issue item, by virtue of their broad use and familiarity, proper placement for maximum information will be second nature to the user. As a result, placing the sensor to use its output in more elaborate configurations will be intuitive.

Follow-on

Subsequent to our laboratory-data analysis, we contracted the developers of devices 1 and 2, as best performers, to reduce the size of their product *without* changing any of its electronics or sensor technology. Results to miniaturize the physical device have been extremely successful. Prototype 1 from Smart Med® (***Appendix E***) is now a production model. This upgrade significantly reduces the device's size by 46% thereby eliminating its field-identified major drawback. The device-case will now fit in a shirt pocket. Prototype 2, the NORE Scope from Medicoustics (upgrade of Sonar Sound™) is a major design breakthrough. Although it appears bulky in its cost-constrained machined-case prototype, it proves that all of the electronic components of the Sonar Sound™ Stethoscope can be incorporated into the sensor-head. Field-identified comments on the Sonar Sound™ regarding noise, as the device is relocated on the patient, are eliminated with the pressure-sensitive *on* switch. The manufacturer claims surface-mount technology can reduce the electronics to *completely* fit within a package smaller than the sensor on the original Sonar Sound (***Appendix E,*** Figure 2) at a weight of approximately 3 ounces, and a battery-life of 200 hours *on-time*. This manufacturer would be ideal candidate for SBIR development.

Based upon our quantitative laboratory data, the two recommended COTS stethoscopes are the SmartMed® Stethoscope (in its upgraded smaller control-box version as specified in ***Appendix F***), and the SonarSound™ Stethoscope, or its miniaturized prototype version the Medicoustics NORE-Scope, (also specified in ***Appendix F***). Other than the fact that the Sonar Sound™ (or its upgrade) is probably more appropriate for measuring blood-pressure in noise-environments well beyond the intended noise-level operating-range, decisions as to which is appropriate for a specific application below 90 dB SPL can be up to the style preferences of the end-user. Laboratory data (Table 5) show that, averaged across environments and across visceral sounds, the SmartMed® is 2.1 dB better in performance than the Sonar Sound device. However as seen in

[11] One specific medical-software product is AMORE from Medivisio Products Helsinki Finland. With this software, visceral sounds can be recorded, identified by sensor location and graphically displayed and played-back within a patient record database.

Table 4, in the HumVee-ambulance noise-environment, both perform equally. Further, the Sonar Sound™ is smaller and uses a more conventional stethoscope headset, which would fit under a field helmet. The prototype upgrade of the Sonar Sound™ (Medicoustics NORE-Scope) is still smaller. The decision on which of these excellent devices is ideal should be based upon the operational needs of the end user. For their abilities to detect the most critical visceral sounds, *any* of the recommended devices will dramatically outperform the conventional stethoscope.

Not surprisingly, these effective devices have been *integrated* with outboard, miniaturized, digital processing hardware for visual presentation and telemetry. Using the COTS product "as is" or with further miniaturization, the possibilities for passive acoustic diagnosis in the battlefield are open.

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APPENDIX A:

NRS WORKING GROUP CONCLUSIONS

NR Stethoscope and Military Need

In broad long-range terms, the *ideal* noise-reducing stethoscope should meet criteria in four areas: 1) have the ability to convey reproducible sounds of interest in a noisy environment, 2) have environmental durability, 3) be easily used by medical and non-medical (emergency-rescue) personnel and, 4) have the potential to transmit, monitor, and store information. Furthermore, there are needs that are specific for the military, in particular the United States Navy (USN), that the stethoscope must meet, such as use in harsh environments, ease of use by Independent Duty Corpsmen (IDCs), and field pack portability and low maintenance. The following is an in depth discussion of the above points.

Fidelity of Extracted Sounds

Primarily, the *ideal* noise reducing stethoscope needs to be a fully functioning stethoscope, which reproduces visceral sounds (heart, lung, bowel) within a noisy environment, either by audible transmission of the sound via headphones, or by a visual translation of the sound to an easy to interpret display - preferably both. Examining current technology, it is judged that two stethoscope models need to be differentiated, since size, complexity, and ultimately cost are related to universality of application. The first device would function in noise from 75 to 90 dB SPL. This model would have a very wide application since most general noise falls within this range. Practical situations include: loud conversation, traffic, ICU settings, ambulance transportation with sirens, and military medical settings such as near generators or equipment, hyperbaric medical pressure chambers, on board submarines and surface ships, and in the battlefield. The second more elaborate device would be required to function in noise up to 130-140 dB SPL. This model would be applicable to <u>extremely</u> noisy environments such as helicopter air-evacuations, and on board vessels with continuous loud impact noise. This model would sacrifice size and low cost for specialized use in limited environments.

The *ideal* stethoscope should be able to detect and accurately reproduce different medical sounds within an organ - especially the heart and lungs. The instrument should be able to detect presence and absence of abnormal heart-rate, important murmurs, and the amplitude of the heart-beat. Also, the presence and absence of various lung sounds should be auscultatable; i.e., breath sounds, wheezes (whistling high frequency sounds found in asthma) as a minimum, and additionally, rales (popping sounds found with fluid/pus/blood in lungs), and rhonchi (lower frequency sounds found in bronchitis).

Environmental Durability

In the military environment, stethoscopes will be required to function under harsh conditions and environments. Extreme temperature conditions should be tolerated, with heat greater than 100 degrees F (desert warfare, boiler rooms aboard surface vessels and submarines, and summer field exercises), and cold less than 0 degrees F (winter warfare, winter field exercises, high-altitude exercises, and cold weather operations). High or low pressure situations should also be tolerated, for example, treatment in hyperbaric medical chambers (used by the USN diving community for diving related injuries), locking in/out of submarines (SEALS/Special Warfare) or general diving operations (marines, combat swimmers, SEALS/Special Warfare), treatment at high altitude during mountain exercises, and medical care delivered on board helicopters and fixed-wing craft during flight. ***Appendix B*** details the physical and other specifications that the *ideal* instrument of the *future* will have to meet.

Utility

Because this medical instrument will often be used in a field environment, it is most important that it be simple to operate. It should be easy to carry and no more cumbersome or outwardly complex than the traditional instrument. It should need infrequent battery or component replacement, be easy to maintain, require minimal quality assurance checks or calibration, and need little additional training prior to use. In military operations the majority of personnel who will be using the stethoscope will be non-physicians. These will include emergency medical technicians (EMTs) and Independent Duty Corpsmen (IDCs). Given the operational requirements, the instrument should be designed for immediate ease of use.

Data Transmission

Telemedicine, the ability to electronically transmit large volumes of medical information, is of increasing importance to the military. This would enable complex data, e.g., lab results, radiographs and even video of physical signs, to be transmitted between remote operational units, where local medical support is minimal, to centers of medical expertise. In order to participate in this process, it is desirable that the *ideal* stethoscope have the ability to store and output its received data in a form that could be electronically transmitted.

Operational Requirements

Below is a summary of the needs of the Navy and of the medical community in regard to the minimum criteria for a feasible noise-reducing stethoscope of the ***future*** without regard to current technological capability. These criteria are a summary of the consensus determined by the working group held in Washington, D. C.

NEEDS OF THE NAVY:

1. Readily portable in the medical field-pack, with minimal supplies.
2. Environmentally hardy to: temperature and pressure extreme, shock, sand, sea, EMI, and corrosion.
3. Easy to use.
4. Require minimal training.
5. Require minimal maintenance and calibration.
6. Capable of storing data in a form for electronic transmission.
7. Capable of being an effective diagnostic instrument within 75 to 90 dB SPL background noise for one model and 90-140 dB SPL for another (which would sacrifice size, complexity, and cost for operation in high noise).
8. Low cost.
9. Capable of being used in a wide range of military settings e.g. SPECWAR, surface/aviation, undersea etc.

APPENDIX B:

SAMPLE *FUTURE END-GOAL* NR STETHOSCOPE SPECIFICATIONS

Ideal Noise Reduction Stethoscope of the Future: base model

SPECIFICATIONS

Case:

Size: (phase 1) 3.25 x 3.25 x 1.25 max.
(Ideal) 3.6 x 2.2 x 1.0" + 1%

Shape: all edges with radius of 0.125 in min.
Maximum Volume (phase 1) 13.2 cu inches
(Ideal) 8.0 cu inches

Integral stainless steel belt clip (either u shaped wire or flat leaf-spring)

Output:

Visual: LCD monochromatic, water-resistant mount, integral with case.

Acoustic: Mini stereo headphone jack wired mono (tip & ring +, sleeve -) Jack housed in water-resistant cavity in case, to protect internal components. Output circuitry load-resistor protected

Digital: Water-resistant connector with enough pins to support an RS-232 compatible output format. 10ft cable with mating water-resistant connector, one end, and RS 232 connector on other end, for computer interface.

Functional:

A water-resistant *three*-button operating system is desirable: The device is activated by simultaneously depressing buttons 1and 2, and memory can be reset by simultaneously depressing all three buttons. Once activated: a single button-press of Button 1, initiates 45-60 sec data-gathering, analysis, alpha numeric display of results, and time-marked storage of both ANR signal and visually displayed data. Entry serially indexed for retrieval. Each additional manual button press results in a similar 45-60 sec data gathering, analysis, display of results, and storage, again sequentially indexed by order of entry. Device holds 10 such data files. Button 2 serially displays stored data files by increasing index number and time of recording. Holding down button 2 rapidly sequences through index of available stored files. Releasing button 2 stops the sequence at the displayed file. Button 3 is used to initiate playback of the currently displayed file. Cycle repeatable. An 1lth entry on button one will remove the earliest entry (1) and renumber all later entries (2 becomes 1 etc.). Device shut-off requires simultaneously depressing buttons 1 and 2. To conserve battery power system shuts down automatically after 10 min. with all data saved.

Environmental:

Operating mechanical shock tolerance: 5G

Operating temperature range - 10 to 110 degrees Fahrenheit

Immunity to salt-water spray

Immunity to EMI

Case water resistant to 10 feet

Operational:

Battery life: 6 months min. under daily 8hr. use 1460 hrs.

MTBF 3,000 hrs.

Noise reduction effective enough to allow full operation in 90 dB broadband pink noise and also in Military and Civilian Ambulances at speeds of 50 MPH

Full operation:

Visually displayed numeric data on Blood Pressure, pulse, respiration, valve sounds and murmurs.

Aurally presented information audible enough for evaluation of pulse, respiration, valve sounds and presence of murmurs.

Suggestions:

Removable Neoprene boot with flap to cover LCD display for added shock protection and covert use.

Adjunct development of add-on piggyback or tethered (belt mounted) infrared transmitter for use with cordless earphone receiver.

Data format and or software to interface with a standard A/D PC sound board during Hyper and Hypo-baric operation

Operation in temperature extremes

APPENDIX C:

ID#:…………….

Noise Reducing Stethoscope
Questionnaire (C-130)

This questionnaire evaluates the performance of noise reducing stethoscopes in various military environments. Your expertise and experience with day-to-day use of stethoscopes makes your answers and comments of extreme importance to this survey. Your comments, positive or negative, will be highly regarded and will be used to make recommendations regarding potential military use.

All the information you provide will be confidential and names will not be associated with the data or reports. Names will only be used as an index for data collection and recovery.

Name:__________________________ Rank/Rate:___________ Date:__________

Command:___________________________ Occupation:_______________________

1. Indicate the number of times you used each stethoscope (i.e. number of patients):

	None	1-5	6-10	11-15	16-20	21(+)
SmartMed:	O	O	O	O	O	O
Sonar Sound:	O	O	O	O	O	O
E-Scope:	O	O	O	O	O	O

Comments:……………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

2. Head/sensor is easy to place and move on the patient:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

3. Head/sensor is easy to stabilize (keep from moving):

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

4. Head/sensor fits comfortably in the hand:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

5. Cable/hose length from the head/sensor to the control box is adequate:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

6. Compared to a conventional stethoscope, the outside noise is minimized:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:…………………………………………………………………………………

7. Control box is easy to operate:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:…………………………………………………………………………………

8. The size of the control box is acceptable:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:…………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
9. Control buttons are easy to reach:					
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
10. Control box is conveniently located on the listener:					
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
11. Control buttons are easy to see:					
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
12. Earpiece/headset is comfortable:					
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
13. Cable length from the earpiece/headset is acceptable:					
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

14. The overall layout (control box, head, earphones) of the stethoscope is adequate:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

15. Compared to the conventional stethoscope, this stethoscope improves my ability to hear heart and lung sounds in a noisy environment:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

15. Stethoscope would improve quality of patient care in a noisy environment:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

16. In a noisy environment, I prefer to use this stethoscope instead of the conventional stethoscope:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

17. Rank the stethoscopes for their effectiveness on the following factors (1=best to 4=worst):

	SmartMed	Sonar Sound	E-Scope	Conventional
Ease of use	___	___	___	___
Ability to reduce noise	___	___	___	___
Ability to hear heart sound	___	___	___	___
Ability to hear lung sound	___	___	___	___

18. Further comments:

SmartMed:…………………………………………………………………………………………………
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Sonar
Sound:………………………………………………………………………………...……………
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E-Scope:…………………………..…………………………………………………………………….
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General:…………………………..…………………………………………………………………….
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Thank you for your time and participation in this study.

ID#:…………….

Noise Reducing Stethoscope
Questionnaire (CVN and CAX)

This questionnaire evaluates the performance of noise reducing stethoscopes in various military environments. Your expertise and experience with day-to-day use of stethoscopes makes your answers and comments of extreme importance to this survey. Your comments, positive or negative, will be highly regarded and will be used to make recommendations regarding potential military use.

All the information you provide will be confidential and names will not be associated with the data or reports. Names will only be used as an index for data collection and recovery.

Name:_________________________ Rank/Rate:___________ Date:__________

Command:__________________________ Occupation:______________________

1. Indicate the number of times you used each stethoscope (i.e. number of patients):

	None	1-5	6-10	11-15	16-20	21(+)
SmartMed:	O	O	O	O	O	O
Sonar Sound:	O	O	O	O	O	O
E-Scope:	O	O	O	O	O	O

Comments:………………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

2. Head/sensor is easy to place and move on the patient:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:………………………………………………………………………………

3. Head/sensor is easy to stabilize (keep from moving):

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

4. Head/sensor fits comfortably in the hand:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:………………………………………………………………………………

5. Cable/hose length from the head/sensor to the control box is adequate:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:………………………………………………………………………………

6. Control box is easy to operate:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:…………………………………………………………………………………

7. The size of the control box is acceptable:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:…………………………………………………………………………………

8. Control buttons are easy to reach:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:…………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

9. Control box is conveniently located on the listener:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

10. Control buttons are easy to see:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

11. Earpiece/headset is comfortable:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:……………………………………………………………………………………

12. Cable length from the earpiece/headset to the control box is acceptable:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O

Comments:……………………………………………………………………………………

13. The overall layout (control box, head, earphones) of the stethoscope is adequate:

SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:……………………………………………………………………………………

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

14. Stethoscope improves my ability to hear heart and lung sounds in a noisy environment:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:………………………………………………………………………………

15. Stethoscope improves my ability to determine blood pressure in a noisy environment:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:………………………………………………………………………………

16. Stethoscope would improve the quality of patient care in a noisy environment:

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
SmartMed:	O	O	O	O	O
Sonar Sound:	O	O	O	O	O
E-Scope:	O	O	O	O	O
Conventional:	O	O	O	O	O

Comments:………………………………………………………………………………

17. In a noisy environment, I would choose to use this stethoscope (circle one):

SmartMed   Sonar Sound   E-Scope   Conventional

Comments:………………………………………………………………………………

18. For the following factors, rank the stethoscopes (1=best to 4=worst) according to their effectiveness in a noisy environment:

	SmartMed	Sonar Sound	E-Scope	Conventional
Ease of use	___	___	___	___
Ability to reduce noise	___	___	___	___
Ability to hear heart sound	___	___	___	___
Ability to hear lung sound	___	___	___	___
Ability to detect blood pressure	___	___	___	___

19. Further comments:

SmartMed:……………………………………………………………………………………………
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Sonar
Sound:……………………………………………………………………………...…………….…
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E-Scope:…………………………………………………………………………………………….
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General:……………………………………………………………………………………………
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Thank you for your time and participation in this study.

APPENDIX D

I. C-130 Group: (*)
II. CVN-74: (&)
III. CAX 10: (+)

Q1: Too much background noise - roaring type. (*)
Sonar Sound best - could hear BP great, others just heard static. Could never hear heart sounds at all with any of them. (*)
Patient variation limited to time/occupational restraints. (+)

Q2: They move very easy. (*)
Movement with the Sonar Sound causes excessive amounts of noise. (&)
Sonar Sound bulky. (+)
Head/Sensor of SmartMed is big. (+)

Q3: SmartMed too small for large handed people. (*)
The Sonar Sound amplifies sound all over the headpiece making it difficult to hold without making additional noise where as the others can be held without worry of hand placement. (&)
Seemed to be very awkward and bulky for SmartMed. (+)
Sonar Sound headpiece not optimal. (+)

Q4: SmartMed head/sensor is too big. (*)
Sonar Sound head is too bulky. (&)
The head/sensor of SmartMed is a discomfort. The head/sensor of Sonar Sound fits very well between the finger, which makes it more stable. (+)

Q5: E-Scope a little short. (+)
Maybe reduce on SmartMed from control box to sensor. (+)

Q6: Control knobs on SmartMed would be better if there were buttons to push. (*)
With SmartMed, dials for volume/filter and size made operation complicated. (+)
SmartMed's control box is big and the switches are knobs instead of push buttons. (+)

Q7: SmartMed control box is too big. (*)
SmartMed too big. (*)
SmartMed too large for handling. (*)
SmartMed's box is a little too large. E-Scope box is great in its location, weight, and size. (&)
SmartMed box is too big! (+)
SmartMed too big. Both SmartMed and Sonar Sound should be configured into one unit like E-Scope. (+)
SmartMed size would not hurt if properly cased with strap. (+)
SmartMed control box too big. (+)
Smaller box for SmartMed. (+)
SmartMed box is way too big. It would definitely be hard to find a spot for it in any medical bag. (+)

Q9: SmartMed control box has too many cords. (*)
SmartMed/Sonar Sound have too much cord length which hinders rapid utilization. (+)

Q10: E-Scope's buttons are small and on the side instead of being in the front. (+)

Q11: Earpiece can be painful when too tight. (*)
Headset was too big on my ears - not snug enough, so it might have made a difference in sound if more snug to ears. (*)
SmartMed's earphones are nice but don't provide enough of a seal around ears. That minor adjustment could make a big difference. (&)
SmartMed is comfortable but bulky. (+)
Sony headset probably too bulky for field use, unless offering an acoustic benefit such as noise canceling. (+)
Headset on SmartMed maybe a little to big and loose, even when reduced to the smallest. Maybe need another inch for it on the smaller side. (+)

Q12: SmartMed and Sonar Sound too long, tangles easily. (+)
SmartMed and Sonar Sound too long. (+)

Q13: SmartMed has too many cords. (*)
SmartMed a little clumsy. (*)
SmartMed box is a little cumbersome (too bulky). (*)
SmartMed too big. Both SmartMed and Sonar Sound should be configured into one unit like E-Scope. (+)
Thought control box on SmartMed could have some casing. (+)

Q14: Sonar Sound picks up too much additional noise. (&)
Only in <u>low vibration</u> background noise. (+)
When environment gets too loud there is not much stethoscope could do. (+)
E-Scope picks up too much outside sound. (+)

Q15: No better than AMAL equivalent. (&)
Had difficulty getting very audible Karotkoff sounds with Sonar Sound. (+)
The SmartMed is more adequate than others are, but all of them would be hard to hear a B/P in a helicopter. (+)

Q16: Could not hear heart or breath sounds - only air craft noise. (*)
Couldn't hear any of them , only finger taps. (*)
I'm not sure that there would be a case where this equipment would be essential. Automated BP machine would be another option. In the case of real combat injuries, accurate BP is irrelevant because IV fluids will be given regardless prior to evac. (+)
Could help with stomach and chest palpitations. (+)

Q17: (Sonar Sound) is more helpful for BPs - but could not hear any heart or breath sounds. Palpation used. (*)
No model that much better than Littmann Cardiology II used. Slightly better than Conventional Littmann. BP and heart-sounds OK, breath-sounds impossible with all methods. (&)

E-Scope provides ease of use and good sound amplification but all of these are worthless a majority of the time on the flight deck. (&)
Very Noisy E-Scope. Moderately noisy Sonar Sound. (&)
Or Littmann Cardio II. (&)
I would use conventional unless I really couldn't hear it, then I'd rather have the more compact, one piece E-Scope. (+)
SmartMed if had a casing that would sit in field bag. (+)
If you could make the SmartMed smaller and easier to stow away it would be the most ideal of all. (+)

Q18b: None actually reduced noise - 3 models actually made it worse for listing to breath sounds. (&)

Q18e: Little difference among all in ability to detect blood pressure. (&)

Q6a: Too much static with SmartMed/(all 3). (*)
Sonar Sound really works well with the BP noise but again unable to hear heart sounds due to static. (*)

Q15a: Could only hear a BP using the Sonar Sound - could not hear HR or SB on any of the products. (*)
Unable to hear heart/lungs with any. (*)

E-Scope:

- Too much plane vibration. (*)
- Again too much outside noise. (*)
- Keep working at it - this is definitely not the answer to noise reduction/hearing ability on stethoscopes. (*)
- Overall the worst. Too noisy. Could not hear heart or lung sounds. (*)
- See Sonar Sound. (&)
- This device was the best for capturing heart and breath sounds. These sounds were at least detectable. In trauma situations this device would be useful. It can detect both heart and a breath sounds and does BP. (&)
- Practical for size but again amplified all noise so sounds are hard to hear. (&)
- This is the consolidated design, which is necessary for ease of use and durability in field. Dial is easy to use. Overall, I felt this was the best although the other models had some advantages under some conditions. (+)
- While testing this unit, I found it to be the most reliable and easiest to handle. It did have limitations when it came to taking BP at close proximity to noise source, but overall a very compact and useful tool. The only drawback would be on durability. The cord connecting the bell/diaphragm to the "box" seems as if it could be damaged easily. (+)
- Best design, maybe improved if noise cancellation tech could be added. (+)
- Overall layout is good. The size is good. Still needs improvement in filtering the noise. (+)
- Would be more comfortable with a headset rather than earpiece. (+)
- As far as compact, this one is the better of the new devices. It does however pick-up too much outside noise. If in a noise enhanced environment and had to choose between regular stethoscope and this unit, I would choose this one. It takes a keen ear to distinguish when hearing for breath sounds. (+)

- If static was reduced in unit, this could be useful unit. (+)

SmartMed

- Good on ground, only fair on plane. (*)
- Too much outside noise to be effective. (*)
- Has good potential with better sound proof headphones. Would be neat if it had the ability to hear heart and lung sounds through earplugs. (*)
- The earphones were too large for my head, so don't know if they were fitted if that would have made a difference. The box I though was too big but length of stethoscope was adequate. (*)
- Headphones helped but were bulky-best of 3 at reducing ambient noise. (&)
- I think it would be a good asset with improvements made on the headset and if the box was reduced a bit. (&)
- This device picks up too much ambient noise and amplifies it. In both low frequency and high frequency environments. Transmittance of ambient sound was intolerable. The headphones do not provide adequate protection against ambient sound either. Blood pressure was accomplished by sheer sound output causing an impulse vibration. (&)
- Awkward to use - would be better if headset was Mickey mouse style - seal off outside noise better. (&)
- Too bulky - both control box and headphones. Lines too easily tangled on self and with other instruments. Filter dial makes little or no difference when I tried it. Heart sounds could be heard <u>and</u> felt in headphones. (+)
- In field testing this device, I did not experience any improvement in quality using the filter aspect. Regardless of the filter setting, a great deal of ambient noise still filtered through. However, I did feel the external headphones provided some benefit. (+)
- Too many parts, good sound but needs streamlining. (+)
- Stethoscope could have been improved with a field case or place in field med bag. Headsets were effective during B/P. This model however was not tested during actual flight. (+)
- The control box should be cut in half. He configuration of the control box should be cut in half. The configuration of the control box should be changed. The switches should be changed to buttons not turn knobs. The headset is good, but not ideal for the field. Good for taking blood pressure. The head/sensor should be changed. (+)
- Control box could be downsized for easier use. (+)
- If the unit was smaller and the length of the hose were smaller it maybe easier to use. The headset was too big and the earphones may need to be a little smaller. The unit was the best at reducing noise unless you move or the patient is moving, such as a bumpy road. It cuts out and becomes static. I believe that in a flight environment it would be useless. I have used a "Propak" in the flight environment and that compared to these is a more efficient and effective tool. (+)
- With a reduction in size of audio cord, earphones and unit size, this is one of the better devices. (+)
- With shortening of the box and reduction in earpiece, the SmartMed would be ideal for a field setting. (+)

Sonar Sound

- Seemed best of three. (*)
- This unit was the only one I could hear a heart beat with. This was only by placing a blood pressure cuff on the patient's arm and listening. (*)
- Outside noise but able to hear sound the best. (*)
- Could be of good use in a noisy environment if further design is done. Great Scope! (*)
- I heard a great BP - loud and clear but had a lot of difficulty hearing heart sounds. I would encourage to further work on getting better with heart sounds and lung sounds. Perfect it if it can be. This was best of all three. (*)
- Increase volume also increased background noise. Filter of no appreciable help. (&)
- Work needs to be done to make the head less sensitive and a place should be made where the examiner could hold the headpiece without fear of hand movement. (&)
- This device picks way too much ambient noise. Ambient sound was deafening and absolutely intolerable. Sounds were indiscernible with all of the noise. I would never use this item in the field. (&)
- Tend to break too soon with bad noise levels but better than others in vibration environment - together with Mickey mouse ears - would probably be good combo. (&)
- Push button controls - not easy to discern status (i.e. need light to indicate on/off or switch so you can easily determine by looking). Also, need lights or digital number to discern volume level, which cannot be determined by looking at buttons on unit. Lines easy to tangle. Head comes off easily - would be lost in field (was lost during testing)! Sound canceling aspect leads to cutting out frequently which makes BP and other measurements difficult with background noise or movement. (+)
- Headpiece unusual, does not look durable and tends to get lost. Needs streamlining.
- The head/sensor is excellent. Has excellent stabilization. Hard to take BP in field. Could hear heart only if patient breathes deeply. (+)
- Would be more comfortable with a headset rather than earpiece. (+)
- Device is very simple to use. If this device could filter out background noise a little better, it would be the one I would use. Device is just the right size for easy carrying. (+)

General

- I will say in fairness to all, I do have a high frequency loss of hearing from being on a C-130 too long but - with a BP cuff I could hear a faint beat with the Sonar Sound. (*)
- While on the ground with outside noises of other C-130s running engines, I could hear heart and breaths sounds. But when we were in the air - could not hear any breath or heart sounds. Was able to hear BP with the sonar sound. SmartMed and E-Scope were unable to pickup any heart or breath sounds. Was thrilled to have the opportunity to test the various stethoscopes. Unfortunately the C-130 has more power. (*)
- None of them drowned out C-130 engine noises! Heard very little with engines! (*)
- It seems that all three could have safety violations because of the noise without our earplugs. A better seal in the ear would be beneficial. (*)
- None of the 3 models improved my ability to hear breath sounds in the areas we tested (Reactor Room and Hanger Bay). Heart sounds were slightly clearer than the Littmann Cardiology II I used. However, neither BP nor BS are significantly improved. (&)
- In most cases a patient on the flight deck who is thought to have an injury which must be

further assessed with a stethoscope will be taken to Main Medical within minutes. The environment is too loud and hazardous to keep a patient there for long. Generally we assess airway, c-spine, breathing, and circulation, put the patient on a stretcher and have them in Main Medical in about 2-8 minutes post the time of injury. (&)

- These devices are good stepping stones. The E-Scope would be very useful and helpful in our environment until better models are developed - especially in our line of work. (&)
- Overall - they did not reduce noise but amplified all noise (body and outside). Good idea but helpful in noisy environment only at certain levels. (&)
- Units must be durable, easy to hold, and hard to tangle or break in field. None of the units worked in high-noise/high-vibration environment of helicopter. Doppler sensors would be superior for heart sounds and possibly BP in high background noise/vibration, but would not work for breath sounds. Visual readout meters would eliminate need for using earphones and may be advantageous in some environments. Small automatic BP units may be necessary in high noise/vibration. (+)
- Again, I suspect only limited benefit would be realized by adoption of any of these models for military use. Regular stethoscopes are fine in most environments, are cheap, durable, and do not require batteries. (+)
- There was no B/P, lung sounds, or heart sounds taken during actual flight. However stethoscopes were effective and helpful while on flight line during turn up prior to flight. (+)
- Can't hear through the Noise. (+)
- Overall I think that all three would help in a noisy environment, but I believe that with a headset the E-Scope would work better. (+)
- Easy to use, hard to hear. (+)

APPENDIX E:

PHOTOS OF DEVICES

Device 1: SmartMed ®

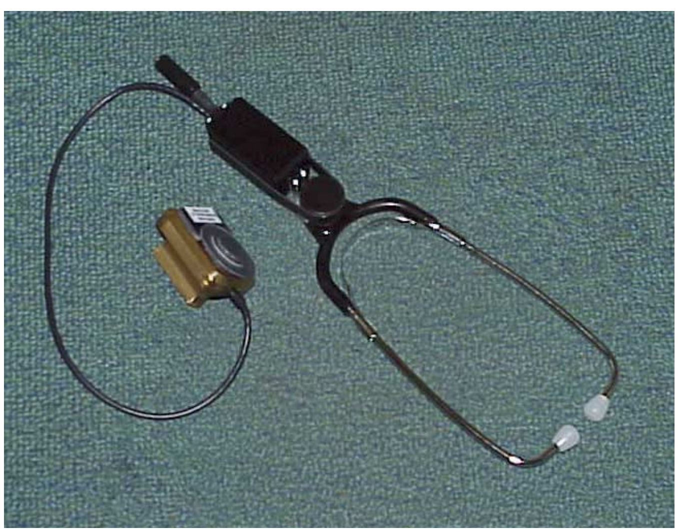
Device 2: Sonar Sound™

Device 3: E-Scope™

APPENDICES

MINIATURIZED VERSIONS OF TESTED MODELS

PROTOTYPE 1: SMARTMED ® PRODUCTION-READY MODEL-UPGRADE.



PROTOTYPE 2: NORE-SCOPE PROOF-OF-CONCEPT PROTOTYPE (UPDATE OF SONARSOUND™)

APPENDIX F:

Updated Device Specifications for Devices 1 and 2 Tested in this Study

Noise Reduction Stethoscope: Upgrade of SmartMed®

SPECIFICATIONS

Operational Description:

Aurally presented visceral information audible enough for evaluation of pulse, respiration, and presence of murmurs in 90 dB SPL pink noise. Sensor-head approximately similar in diameter and shape to a conventional stethoscope. Must have an electronic IC amp-buffered output. Must have noise reducing capabilities and signal fidelity equal to or better than the C. F. Electronics Smart Med Stethoscope in a smaller package.

Physical Characteristics, *Case*:

Size: approximately 11.3 x 7x 4.5 cm ±2%, 380 cubic cm maximum.
Shape: all edges radiused.
Integral stainless steel belt clip (either U shaped wire or flat leaf-spring)

PHYSICAL CHARACTERISTICS, *STETHOSCOPE HEAD*:

Size: diameter, 5 cm or less
thickness 2.2 cm or less
Moldex (NAMRL) or equal noise-attenuating coating on back of head.

PHYSICAL CHARACTERISTICS, *CABLING* - HEAD TO CASE

Coiled cord (retracted) 70 cm max., (extended) 55 cm min.

PHYSICAL CHARACTERISTICS, *OUTPUT*:

Acoustic: Mini stereo headphone jack wired mono (tip & ring +, sleeve -).
Output circuitry load-resistor protected, IC amplified.
Closed circumaural headset provided.

ELECTRICAL CHARACTERISTICS, *OUTPUT*:

.5v RMS
capable of driving any headset of 10 to 200 ohms

FUNCTIONAL CHARACTERISTICS:

On/off switch, volume control, variable filter, battery operated, automatic shut-off

OPERATIONAL CHARACTERISTICS:

Noise reduction effective enough to allow full operation in up to 90 dB SPL noise field.

Suggestions:

Acoustic output to be presented over a pair of closed circumaural headphones (supplied) or insert earphones embedded in noise-attenuating-foam earplugs. Additional attenuation is available with circumaural passive hearing protectors worn over the insert earphones. Alternate use of self-powered active-noise-cancellation (ANC) headsets/flight-helmets is possible if needed.

APPENDICES

Updated Device Specifications for Devices 1 and 2 Tested in this Study

Noise Reduction Stethoscope: Upgrade of Sonar Sound ™

SPECIFICATIONS

Operational Description:

Aurally presented visceral information audible enough for evaluation of pulse, respiration, and presence of murmurs in 90 dB SPL pink noise. Sensor-head integral with electronics. Must use thin sheet PVDF (Polyvinylidene Fluoride) piezoelectric polymer sensor material to gain immunity from airborne noise. Electronic IC amp-buffered output required. Noise-reducing capabilities and signal fidelity will be equal to or better than Sonar Sound Stethoscope in a smaller package.

Physical Characteristics, *Case*, including sensor head:

Size: approximately 6.5 x 5.0 x 3.75 cm ±2%, 124.5 cubic cm max.
Shape: all edges radiused.

Physical Characteristics, *Output*:

Acoustic: Mini stereo headphone jack, wired mono.
Output circuitry load-resistor protected, IC amplified.
Earpiece-headset provided.
Battery compartment inline on headphone cord.

Electrical Characteristics, *Output*:

Bandwidth: 100 to 1000 Hz
Level: approx. .4v RMS @ 1kHz
Capable of driving any headset of 125 ohms or greater.

Functional Characteristics:

Hold-down on/off switch, volume control, battery operated

Operational Characteristics:

Noise-reduction effective enough to allow full operation in up to 90 dB SPL noise field.

SUGGESTIONS:

Acoustic output shall be presented over a pair of stethoscope earphones (supplied) or insert earphones embedded in noise-attenuating-foam earplugs (user supplied). Additional attenuation is available with circumaural passive hearing protectors worn over the insert earphones. Alternate use of self-powered active-noise-cancellation (ANC) headsets/flight-helmets is possible if needed.